UNITED NATIONS

UNEP

Food and Agriculture Organization of the United Nations

RC

UNEP/FAO/RC/CRC.11/2

Distr.: General
29 June 2015

Original: English

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Eleventh meeting
Rome, 26–28 October 2015
Item 5 (a) (i) of the provisional agenda*

Technical work: consideration of draft decision guidance documents: short-chained chlorinated paraffins

Draft decision guidance document for short-chained chlorinated paraffins

Note by the Secretariat

I. Introduction

1. At its tenth meeting, the Chemical Review Committee reviewed notifications of final regulatory action for short-chained chlorinated paraffins submitted by Canada and Norway, together with the supporting documentation referenced therein, and concluded that the requirements set out in Annex II to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade had been met.

2. In its decision CRC-10/4, the Committee recommended that the Conference of the Parties list short-chained chlorinated paraffins in Annex III to the Convention as industrial chemicals. By the same decision, the Committee adopted a rationale for its conclusions and agreed to establish an intersessional drafting group to produce a draft decision guidance document.[1] A detailed workplan for the development of the decision guidance document was prepared by the Committee in line with the process adopted by the Conference of the Parties by decision RC-2/2 and amended by decisions RC-6/3 and RC-7/3. The recommendation, rationale and workplan were annexed to the report of the Committee on the work of its tenth meeting (UNEP/FAO/RC/CRC.10/10, annexes I and III).

3. The material available to the intersessional drafting group included a summary of the outcome of the tenth meeting of the Committee, a copy of a working paper on the preparation of internal proposals and decision guidance documents for banned and severely restricted chemicals and the notifications of final regulatory actions and associated supporting documentation available to the Committee at its tenth meeting.

* UNEP/FAO/RC/CRC.11/1.

[1] The members of the intersessional drafting group were: Ms. Anja Bartels (Austria), Mr. Gilberto Fillman (Brazil), Ms. Parvoleta Angelova Luleva (Bulgaria), Mr. Jeffery R. Goodman (Canada), Ms. Jinye Sun (China), Mr. Mohammed Ali Mohammed (Ethiopia), Ms. Mirijam Kristina Brigitta Seng (Germany), Ms. Ana Ramirez (Honduras), Mr. Arturo Gavilán (Mexico), Ms. Amal Lemsioui (Morocco), Ms. Leonarda van Leeuwen (Netherlands), Mr. Jung-Kwan Seo (Republic of Korea), Mr. Jürgen Helbig (Spain), Ms. Nuansri Tayaputch (Thailand) and Mr. Boniface Mbewe (Zambia).

K1501989 270815

4. In accordance with the agreed workplan, the co-coordinators of the intersessional drafting group, Ms. Leonarda van Leeuwen (Netherlands) and Ms. Ana Ramirez (Honduras), in consultation with the Secretariat, prepared an internal proposal based on the notifications and the supporting documentation. That internal proposal was circulated to the members of the drafting group for comments on 19 January 2015. It was amended in the light of the comments received and was circulated on 20 February 2015 to all Committee members and to the observers who had attended the tenth meeting. Responses were received from Committee members and observers and taken into consideration in the revision of the draft decision guidance document.

5. The outcomes of the work of the intersessional drafting group, including a compilation of the comments received and the draft decision guidance document, were circulated to the members of the drafting group on 1 May 2015.

6. The text of the draft decision guidance document is set out in the annex to the present note. It has not been formally edited. A tabular summary of the comments received, including information on how they were addressed, is set out in document UNEP/FAO/RC/CRC.11/INF/7.

II. Proposed action

7. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list short-chained chlorinated paraffins in Annex III to the Convention as industrial chemicals, for consideration by the Conference of the Parties at its eighth meeting.

Annex

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Draft
Decision Guidance Document

short-chained chlorinated paraffins

Food and Agriculture Organization of the United Nations

Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Note to the reader

The paragraphs with square brackets for consideration by the Chemical Review Committee at its eleventh meeting are highlighted.

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its […] meeting, held in […] on […], the Conference of the Parties agreed to list Short-chained chlorinated paraffins in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention.
Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

[1] According to the Convention, the term "chemical" means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term "Party" means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

Standard core set of abbreviations[3]

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
CA	chlorinated alkanes
cc	cubic centimetre
cm	centimetre
CP	chlorinated paraffins
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment of the European Commission
CTV	critical toxicity value
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Chemical Substances
EU	European Union

[3] This core list should serve as the basis for DGDs for industrial chemicals, pesticides and severely hazardous pesticide formulations. It should be augmented by abbreviations used in the individual DGDs relevant to the chemical(s) in question.

Definitions and spelling should, as far as practicable, follow the IUPAC glossary of terms in toxicology and the IUPAC glossary of terms relating to pesticides in their current editions.

As a general rule it is preferable that acronyms used only once in the text be spelled out rather than included in the list of abbreviations.

STANDARD CORE SET OF ABBREVIATIONS	
EUSES	European Union System for the Evaluation of Substances
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LCCP	long-chained chlorinated paraffins
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
m	metre
MCCP	medium-chained chlorinated paraffins
m.p.	melting point
mg	milligram
ml	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	Maximum Tolerated Dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
NP	nonylphenol
NPE	nonylphenolethoxylates
OECD	Organisation for Economic Co-operation and Development
OSPAR Convention	Convention for the Protection of the Marine Environment of the North-East Atlantic
PEC	predicted environmental concentration
POPRC	Persistent Organic Pollutants Review Committee
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).

STANDARD CORE SET OF ABBREVIATIONS	
RfD	reference dose (for chronic oral exposure; comparable to ADI)
SCCP	short-chained chlorinated paraffins
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TDI	tolerable daily intake
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNECE	United Nations Economic Commission for Europe
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision guidance document for a banned or severely restricted chemical

SHORT-CHAINED CHLORINATED PARAFFINS **Published:**

1. Identification and uses (see Annex 1 for further details)

Common name

Short-chained chlorinated paraffins (SCCP)
Various abbreviations for (short-chained) chlorinated paraffins are used in the underlying documentation for this DGD. For clarification purposes, only the abbreviations SCCP or CP are used in this report.

Chemical name and other names or synonyms

Alkanes, C_{10-13}, chloro; Chlorinated paraffins with a chlorination degree of more than 48% by weight.

Molecular formula

$C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13 (European Chemicals Bureau (2000).

CAS-No.(s)

The molecular formula of SCCP ($C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13) describes multiple chemicals, and SCCP occur in complex mixtures. This DGD refers to all SCCP as described by the molecular formula. A non-exhaustive list of chemical names and CAS numbers for SCCP is given below.

Chemical name	CAS number
alkanes, C10-13, chloro; chlorinated paraffins, C10-13	85535-84-8
Chlorowax	51990-12-6
Alkanes, chloro	61788-76-9
Paraffin waxes and hydrocarbon waxes, chloro	63449-39-8
Paraffin waxes and hydrocarbon waxes, chlorosulfonated	68188-19-2
Hydrocarbons, C_{2-6}, chloro	68476-48-2
Hydrocarbons, C_{1-6}, chloro	68606-33-7
Alkanes, chloro, sulfurized	68911-63-7
Alkanes, C_{6-18}, chloro	68920-70-7
Paraffin waxes and hydrocarbon waxes, chloro, reaction products with naphthalene	68938-42-1
Alkanes, C_{10-18}, bromo chloro	68955-41-9
Alkanes, C_{11-14}, 2-chloro	68990-22-7
Alkanes, C_{12-13}, chloro	71011-12-6
Paraffin waxes and hydrocarbon waxes, chloro, sulfonated, ammonium salts	72854-22-9
Paraffins (petroleum), normal C_{8-20}, chlorosulfonated, ammonium salts	73138-78-0
Alkanes, C_{10-21}, chloro	84082-38-2
Alkanes, C_{10-32}, chloro	84776-06-7
Paraffin oils, chloro	85422-92-0
Alkanes, C_{12-14}, chloro	85536-22-7
Alkanes, C_{10-14}, chloro	85681-73-8
Paraffins (petroleum), normal C>10, chloro	9753-43-0

Alkanes, C_{10-26}, chloro	**97659-46-6**
Alkanes, C_{10-22}, chloro	**104984-36-9**
Alkanes, C_{10-12}, chloro	**108171-26-2**
1-chlorododecane	**112-52-7**
1-chlorodecane	**1002-69-3**
1,10-dichlorodecane	**2162-98-3**
1,12-dichlorododecane	**3922-28-9**

Harmonized System Customs Code

3824.9

Other numbers

-

Category

Industrial

Regulated category

Industrial chemical

Use(s) in regulated category

Norway
The notified regulatory action relates to SCCP and the industrial use of the chemical as softeners in paints, plastics, fillers and coatings, as flame inhibitors in rubber, plastics and textiles, and as additives in other chemical substances and products. There has also been limited use in metal working fluids as well as in certain lubricants and car care products. (UNEP/FAO/RC/CRC.10/6 section 1.7.2).

Canada
The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. The final regulatory action states that all manufacture, use, sale, offer for sale or import of SCCP or products containing them is prohibited, unless SCCP are incidentally present in the product or if they are used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).

[Stockholm Convention
According to the draft risk profile on SCCP, that was developed by the Persistent Organic Pollutants Review Committee (POPRC) of the Stockholm Convention, SCCP are used or have been used in the following sectors (POPRC, 2012, p.9):

Application/Use	% by Weight of Final Product	Types of Releases	Amounts Released	Reference
Metalworking lubricants		Loss at production/ formulation site	Controlled CP losses of 1-2%; 0.06 g/kg CP consumed; loss of 23 tonnes SCCP /year in mid-1990s in Europe; default emission factors for CP are 0.005% to air and 0.25% to wastewater before on-site treatment	EC (2000); KEMI (1991); EU (2003)
		Loss from use	Carry-off from work pieces is 2.5 kg/site/year for small user (100-L capacity) and 2,500 kg/site/year for larger user (95,000-L capacity); annual losses of CP from cutting fluid are 48%, 75% and 100% for large, medium and small machine shops; 18% loss of SCCP to wastewater (733 tonnes/year in 1998 in the EU) and 3% disposed in landfill from use in metalworking fluids; 10% discharged to wastewater from use in water-based metalworking fluids; loss of CP are 18.5% and 31.6% for oil-based and water-based metalworking fluids, respectively. Default emission factors for CP are 0.02% to air for both types of fluids.	Government of Canada (1993); EC (2000); U.K. Environment Agency (2003a)
Paints, adhesives and sealants	5-15% CP (paints) 10-15% CP (typically for sealant) Up to 20% CP for some applications (sealant)	Loss at production/formulation site	Insignificant (paint); Low or zero (sealants); 5% solid waste (sealants)	Zitko and Arsenault (1974); U.K. Environment Agency (2003b)
		Loss from use/application	Waste during application may be disposed in landfill sites; default emission factors for thermosetting resins are 0% to air and 0.1% MCCP and LCCP s to wastewater	BRE (1998); U.K. Environment Agency (2003a)
		Loss from leaching	Emission factor of 0.15%/year for MCCP	U.K. Environment Agency (2003a)
Leather fat liquors	1% SCCP or less (EU only)			EU Directive 2002/45/EC
Plastics and rubber	10.1-16.8% CP (conveyor belts) 6.5% CP (shoe soles) 13% CP Industrial sheeting)	Loss at production/ formulation site	Default emission factors for plastic additives are 0.1% to air and 0.05% CP to wastewater; default emission factors for thermosetting resins are 0% to air and 0.05% CP to wastewater	BRMA (2001); U.K. Environment Agency (2001); BRE (1998)
		Loss from use	Loss during wear and abrasion of products	
		Losses from volatilization	0.05% during lifetime of product	
Flame retardants	1-4% CP (typically) Up to 15% CP for some applications 1-10% SCCP added to rubber			Zitko and Arsenault (1974); BUA (1992)
Textiles and polymeric materials		Loss at production/ formulation site	17% of SCCP use in 1998	EC (2000)

Trade names	A70 (wax); Chloroflo; Adekacizer E; Chlorparaffin; Arubren; Chlorowax; Cereclor; Cloparin; Chlorcosane; Cloparol; Chlorez; Clorafin; Chlorofin; CW; Derminolfett; Derminolol; EDC-tar; Electrofine; Enpara; Hordaflam; Horda-flex; Hordalub; Hulz; Khp; Meflex; Monocizer; Paroil; Poliks; Tenekil; Toyoparax; Unichlor. *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	not relevant
Uses in other categories	Canada and Norway No reported use as pesticide.
Basic manufacturers	**[CP (of various chain lengths) are currently produced in the United States, the EU, Russia, India, China, Japan, Brazil and Slovakia.** **However, the use of SCCPs has been phased-out in the United States, through a consent decree between the U.S. government and the last manufacturer of the chemical** **SCCP are no longer produced in Germany since 1995. Prior to 1995, Clariant, Hoechst, and Huels produced SCCP in Germany. Hoechst produced between 9300 and 19300 tonnes/ year in the period 1993 to 1995 (UNEP/POPS/POPRC.8/6, p.7-9).]** *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

SCCP are included in the PIC procedure as industrial chemicals. They are listed on the basis of final regulatory actions notified by Norway and Canada that ban their use as industrial chemicals.

No final regulatory actions relating to pesticidal uses of SCCP have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

Norway

The use of SCCP is banned by the final regulatory action which states that production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 sections 2 and, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).

Reason: Environment

Canada

The use of SCCP is banned by the final regulatory action which entered into force on 14 March 2013 which states that after the above mentioned date, all manufacture, use, sale, offering for sale or import of SCCP or products containing them is prohibited, unless incidentally present in a product or if used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 sections 2.1, 2.2.1 and 2.2.3).

Reason: Human Health and Environment

2.2 Risk evaluation (see Annex 1 for further details)

Norway

SCCP are very toxic to aquatic organisms, they degrade slowly in the environment and have a high potential for bioaccumulation. These properties, together with the potential for long range transport via air and water, confirmed by monitoring data, give rise to serious concerns for long term effects in the aquatic environment (UNEP/FAO/RC/CRC.10/6 Annex I, section 2.3).

The use of SCCP in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures. Possible risks to sediment-dwelling organisms were identified as a result of the production of short chained chlorinated paraffins, formulation and use of metal cutting fluids and formulation and use of leather finishing products and, use in rubber formulations. There is a possible risk to soil-dwelling organisms in agricultural soils at a local level (for metal working fluid formulation and use, and leather finishing formulation and use) and at a regional level due to spreading of sewage sludge. Further information for the soil and sediment

compartments could be gathered to clarify the risk. However, risk reduction methods should be considered for metal working since further information (either on exposure or aquatic toxicity) is unlikely to change significantly the PEC/PNEC ratios calculated for aquatic organisms. Based on the available data, a risk to aquatic organisms cannot be excluded for leather finishing applications either and so risk reduction measures should also be considered for that use (UNEP/FAO/RC/CRC.10/INF/10, p. 136).

Canada

On the basis of the available information, the latest assessment report from 2008 concluded that SCCP are entering, or may enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).

The risk evaluation considered all Chlorinated Alkanes (CA) including SCCP, Medium-Chain Chlorinated Alkanes (MCCA) and Long-Chain Chlorinated Alkanes (LCCA). There are no known natural sources of CA. The major sources of release of CA into the Canadian environment are likely the formulation and manufacturing of products containing CA, such as polyvinyl chloride (PVC) plastics, and use in metalworking fluids. The possible sources of releases to water from manufacturing include spills, facility wash-down and drum rinsing/disposal. CA in metalworking/metal cutting fluids may also be released to aquatic environments from drum disposal, carry-off and spent bath. These releases are collected in sewer systems and often ultimately end up in the effluents of sewage treatment plants. When released to the environment, CA tend to partition primarily to sediment or soil (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

In Canada, SCCP have been detected in the following environmental media: Arctic air, sediments from remote northern lakes, sewage treatment plant effluents from southern Ontario, surface water, sediments and fish from Lake Ontario and marine mammals from the Canadian Arctic and the St. Lawrence River. Maximum Canadian concentrations of SCCP were observed in aquatic biota and sediments from the St. Lawrence River and also in sediments and fish from south-western Ontario. Atmospheric half-lives for many CA are estimated to be greater than 2 days. In addition, SCCP have been detected in Arctic biota and lake sediments in the absence of significant sources of SCCP in this region, which suggests that long-range atmospheric transport of SCCP is occurring. SCCP residues have been detected in Canadian lake sediments dating back over 25 years, suggesting that the half-lives of SCCP in sediment are greater than 1 year. It is therefore concluded that SCCP are persistent as defined in the *Persistence and Bioaccumulation Regulations* of the *Canadian Environmental Protection Act, 1999* (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

Based on the information available, it was concluded that SCCP were entering the environment in quantities or concentrations or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity (UNEP/FAO/RC/CRC.10/6 section 2.4.2.2).

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Norway The regulatory action notified by Norway bansthe use of SCCP as industrial chemicals. Production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 section 2, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).

The regulation entered into force on 1 January 2001. However, stock items imported or produced before 1 January 2001 were allowed to be sold and used until 1 January 2002. As stated in OSPAR decision 95/1, there was a transition period until 1 January 2005 for conveyor belts used in the mining industry and for sealing materials in dams containing SCCP. However, such applications were not relevant in Norway (UNEP/FAO/RC/CRC.10/6 section 2.2.3).

Canada The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. All manufacture, use, sale, offer for sale or import of SCCP is banned by the final regulatory action which entered into force on 14 March 2013.

The final regulatory action states that after the above mentioned date, all manufacture, use, sale, offer for sale or import of SCCP or products containing them are prohibited, unless the SCCP are incidentally present in the product, or if they are used in laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).

3.2 Other measures to reduce exposure

UNECE LRTAP and OSPAR

In August 2005, the European Union proposed SCCP to be added to the UNECE Convention on Long Range Transboundary Air Pollution (CLRTAP), Aarhus Protocol on Persistent Organic Pollutants. SCCP were proposed to meet the criteria of decision 1998/2 of the Executive Body for persistence, potential to cause adverse effects, bioaccumulation and potential for long range transport. At the 24th session of the Executive Body in December 2006, the Parties to the UNECE POPs Protocol agreed that SCCP should be considered as a POP as defined under the Protocol, and requested that the Task Force continues with the Track B reviews of the substances and explores management strategies for them. SCCP were added to Annexes I and II of the 1998 Aarhus Protocol in December 2009 at the 27th session of the Executive Body. Annex II restricts SCCP uses to fire retardants in rubber used in conveyor belts in the mining industry and in dam sealants, and states that action to eliminate these remaining uses should occur once suitable alternatives are available.

In 1995, the OSPAR Commission for the Protection of Marine Environment of the North-East Atlantic adopted a decision on SCCP (Decision 95/1). That decision established a ban of the use of SCCP in all areas of application. Under that decision, all sale and use of SCCP were to be prohibited by the end of 1999. Exemptions were to allow for the use of SCCP in dam sealants and underground conveyor belts until 2004.

In 2006, OSPAR prepared an overview assessment of the implementation of PARCOM Decision 95/1 on SCCP (OSPAR, 2006). The assessment was based on national implementation reports received from nine of 15 Contracting Parties which have been requested to submit, in the 2005/2006 meeting cycle, reports on the national measures taken in the context of that decision. All reporting Contracting Parties have taken measures to implement PARCOM Decision 95/1. Some Contracting Parties reported a full ban of all or certain uses of SCCP and reductions of other uses. In general, Contracting Party measures have addressed the uses in metalworking and for fat liquoring of leather.

Similar to OSPAR, the Baltic Marine Environment Protection Commission (HELCOM) has included SCCP in their list of harmful substances. On November 15, 2007, HELCOM included SCCP in the HELCOM Baltic Sea Action Plan. Contracting Parties to HELCOM have agreed, starting in 2008, to work for strict restriction on the use in the whole Baltic Sea catchment area of the Contracting States of several hazardous substances, including SCCP. Hazardous substances are those found to be PBT or vPvB (Annex E 2010 submission from Lithuania) (POPRC, 2012).

3.3 Alternatives

Canada

In determining risk management options, the risks and costs of potential alternative substances and technologies were considered.

Metalworking Fluids

There are two approaches to minimizing the releases of CP within the metalworking industry, specifically to: (i) increase the adoption rate of substitutes to CP among metalworking fluid formulators and end-users; and (ii) increase the adoption of best management practices by end-users of metalworking fluids.

Although substitutes to CP are available to metalworking fluid formulators, several issues need to be considered in their implementation, as some potential alternatives are:

- not technically suitable for all applications;
- more costly; and
- may also pose environmental and health risks.

Polyvinyl Chloride

In PVC manufacturing, CP were used primarily in applications where moderate plasticizing and flame retardant properties were required at low cost. Moreover, it was not anticipated that there would be many technical obstacles if CP had to be replaced with alternative plasticizers and/or flame retardants. Analysis of CP alternatives suggests that, in many cases, the overall technical characteristics of the PVC product such as flexibility and stability would improve with the use of alternatives. Although technically feasible, the use of these alternatives would likely increase the raw material costs for manufacturers and they may also pose environmental and health risks.

Paints and Coatings, Adhesives and Sealants, and Rubber and Elastomers

Very small quantities of CP are used annually in Canada in the formulation of paints and coatings, adhesives and sealants, and rubber and elastomers relative to metalworking fluids and PVC. Less than 100 tonnes of both MCCP and LCCP were reported to Environment Canada for the year 2001. The favourable characteristics provided by CP include good compatibility with the resin systems where they are used; they are colourless; they are non-volatile and do not add to volatile organic compounds (VOC) content of a coating system; and they have low viscosity.

The use of CP in the rubber industry has historically involved the utilization of SCCP to manufacture rubberized conveyor belts for the underground mining industry as well as other technical products such as hoses and gaskets. They are used in these applications because of their superior flame retardant properties, which are often required in order to meet fire standard codes for products.

Technical barriers have been reported for adhesives and sealants substitutes as well; the primary technical issue was that they are more prone to bleeding from the sealant product, thus directly affecting the durability of the sealant and the substrate (Environment Canada, Health Canada, 2008).

OSPAR

MCCP, the medium chained chlorinated paraffins (C14-17) may have similar uses to SCCP and are used as replacements for SCCP as extreme pressure additives in metalworking fluids, as plasticisers in paint, and as additives in sealants.

The United Kingdom risk assessment on MCCP, in the framework of the Existing Substances Regulation, states that some risk reduction measures are required for uses in the production of PVC, in some process formulations of metal cutting fluids, in emulsifiable metal cutting/working fluids where the spent fluid is discharged to waste water, in leather fat liquors and in carbonless copy paper during recycling. The risk from use in oil-based metal cutting fluids may also be of concern.

LCCP, the long chained chlorinated paraffins have been used in some demanding applications in metalworking fluids instead of SCCP in Sweden. LCCP are also suggested as a replacement to SCCP in the leather industry as well as in paint and coatings, in sealants and rubber.

Alkyl phosphate esters and sulfonated fatty acid esters may function as replacements for SCCP as extreme pressure additives in metalworking fluids. Natural animal and vegetable oils are also alternatives in the leather industry. In paint and coatings, phthalate esters, polyacrylic esters, diisobutyrate as well as phosphate and boron-containing compounds are suggested as replacements.

Phthalates esters are alternatives for use in sealants. Alternatives as flame retardant in rubber, textiles and PVC are antimony trioxide, aluminium hydroxide, acrylic polymers and phosphate containing compounds. Sweden

considers these substances as being less harmful than chlorinated paraffins.

However, there might still be uses for which these alternatives do not fulfil all technical and security demands. In addition, the cost of substitution may not be proportional to health and environmental advantages for all types of applications. Risk reduction measures like closed production and/or further regulation of emission limits, are amongst several measures that could be taken into account.

It was agreed at the OECD Expert Meeting on SCCP and NP/NPEs, hosted by Switzerland on 8 - 10 November 1999, that some form of exchange of information on substitute chemicals and processes is desirable. A password protected web site has been established by the OECD Secretariat (OSPAR, 2009).

3.4 Socio-economic effects

Canada

Socio-economic considerations for CP included a qualitative analysis of costs to industry in terms of switching to alternatives and benefits to the public.

It was determined that the cost of using alternative substances would have a minimal economic effect for most uses. However, where the costs of alternatives are significant there would be an increase in the raw material costs for manufacturers that are currently using CP in their products. This increase, along with other re-formulation costs, could hinder the competitiveness of these products in domestic and foreign markets (Environment Canada, Health Canada, 2008).

At the time the regulation came into force, SCCP were not manufactured in Canada. Also, the use of SCCP was phased out by industry in early 2010. As a result, the Regulations were not expected to result in any incremental costs to industries. However, the Regulations prevent a re-introduction of these substances and of products containing them in the Canadian market, thereby eliminating the risk of release of SCCP and resulting ecological harm. Furthermore, they serve to reduce any potential transboundary emissions of SCCP and protect the environment from its risks on a global level, signalling Canada's commitment to take action on SCCP to its international partners. (UNEP/FAO/RC/CRC.10/6 section 2.5.3.1).

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	-
IARC	2B – Possible carcinogen to humans
European Community	In accordance to Regulation (EC) No 1272/2008, which implements the UN GHS in the EU: **Hazard Class, Category Code and Hazard Statement Code** Carc. 2; H351 – Suspected of causing cancer Aquatic Acute 1; H400 – Very toxic to aquatic life Aquatic Chronic 1; H410 – Very toxic to aquatic life with long-lasting effects **Pictograms, Signal Word Codes** Environment GHS09: Health hazard GHS 08: In accordance with Council Directive 67/548/EEC: **Carc. Cat. 3; R40** – Limited evidence of a carcinogenic effect. **R66** – Repeated exposure may cause skin dryness or cracking. **N** - Dangerous for the environment. **R50-53** – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
US EPA	SCCPs are persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations. They can remain in the environment for a significant amount of time and can bioaccumulate in animal tissues, increasing the probability and duration of exposure. Even relatively small releases of these chemicals from individual manufacturing, processing, or waste management facilities have the potential to accumulate over time to higher levels and cause significant adverse impacts on the environment. SCCPs have been measured in a variety of environmental media including air, sediment, surface waters, and wastewater. SCCPs have also been measured in a variety of biota, including freshwater aquatic species, marine mammals, and avian and terrestrial wildlife. In addition, SCCPs have been detected in samples of human breast milk from Canada and the United Kingdom, as well as in a variety of food items from Japan and various regions of Europe. (U.S. EPA Short-Chain chlorinated Paraffins (SCCPs) Action Plan: http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/sccps_ap_2009_1230_final.pdf)

4.2 Exposure limits

IPCS (1996):

On the basis of available data on repeated dose toxicity, **a Tolerable Daily Intake (TDI) for non-neoplastic effects of SCCP for the general population can be developed:**

TDI = 10 mg/kg body weight per day / 100 = 100 µg/kg body weight per day;

where 10 mg/kg body weight per day is the lowest reported no-observed-effect level (increases in liver and kidney weights and hypertrophy of the liver and thyroid at the next highest dose in a 13-week study on rats); and 100 is the uncertainty factor (× 10 for interspecies variation; × 10 for intraspecies variation).

On the basis of multistage modelling of the tumours with highest incidence (hepatocellular adenomas or carcinomas (combined) in male mice) in the carcinogenesis bioassay with SCCP, the estimated dose associated with a 5% increase in tumour incidence is 11 mg/kg body weight per day (amortized for period of administration). After dividing this value by 1000 (uncertainty factor for a non-genotoxic carcinogen), it can be recommended that **daily doses of SCCP for the general population should not exceed 11 µg/kg body weight, on the basis of neoplastic effects**.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	Chlorinated paraffins (C10-C30): Hazard Class: UN: 9 Packing Group: UN: III (United Nations, 2013)
International Maritime Dangerous Goods (IMDG) Code	Chlorinated paraffins (C10-C30): UN 3082 Environmentally hazardous substance, liquid, N.O.S. Class 9 (IMO, 2013)
Transport Emergency Card	Not available

4.4 First aid

4.5 Waste management

Since chlorinated paraffins are bioaccumulative and toxic to environmental organisms and owing to difficulties in monitoring environmental levels, it is recommended that use and disposal of these compounds should be controlled to avoid release to the environment.

Disposal of wastes containing chlorinated paraffins occurs through resource recovery, destructive incineration or landfill, usually on disposal sites for special wastes and in compliance with local regulations. Owing to their thermal instability, chlorinated paraffins are expected to be degraded by incineration at low temperatures and thus would not be expected to volatilize in exhaust gases from an incinerator. However, in a study by Bergman et al. (1984), chlorinated aromatic compounds such as PCBs, naphthalenes and benzenes were formed by pyrolysis of chlorinated paraffins (see section 4.2.1) although the conditions used were not identical to the operation conditions of waste incineration plants. Chlorinated paraffins are not expected to be formed *de novo*. The disposal of chlorinated paraffins in landfills may give rise to leaching into water, but owing to the low water solubility and strong adsorption onto solids the amounts reaching water are likely to be low. (IPCS 1996)

Annexes

Annex 1	**Further information on the substance**
Annex 2	**Details on Final regulatory action**
Annex 3	**Address of designated national authorities**
Annex 4	**References**

Annex 1 Further information on the substance

Introduction

The information presented in the present annex reflects the conclusions of the two notifying Parties, namely Norway and Canada. Where possible, information provided by these two Parties on hazards has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions banning short-chained chlorinated paraffins.

The notification from Canada was first reported in PIC Circular XXXVIII of December 2013 and the notification from Norway in PIC Circular XV of June 2002.

Annex 1 – Further information on *short-chained chlorinated paraffins*

1.	Physico-Chemical properties	
1.1	**Identity**	The molecular formula of SCCP ($C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13) describes multiple chemicals, and SCCP occur in complex mixtures. This DGD refers to all SCCP as described by the molecular formula. A non-exhaustive list of chemical names and CAS numbers for SCCP is given in section 1 of this DGD.
1.2	**Formula**	$C_xH_{(2x-y+2)}Cl_y$, where x=10-13 and y=1-13 (European Communities, 2000)
1.3	**Colour and Texture**	clear to yellowish liquid (ECB, 2000)
1.4	**Decomposition temperature**	-
1.6	**Density (g/cm^3)**	-
1.7	**Resistance to acids**	-
1.8	**Resistance to alkalis**	-
1.9	**Tensile strength (10^3 kg/cm^2)**	-

2	Toxicological properties	
2.1	**General**	
2.1.1	**Mode of Action**	Narcotic
2.1.2	**Symptoms of poisoning**	-
2.1.3	**Absorption, distribution, excretion and metabolism in mammals**	In general there is very limited information on the toxicokinetics of SCCP and there is no information with respect to differing chain length and degree of chlorination. No information is available on the toxicokinetics of these substances following inhalation or dermal exposure in animals. However the physicochemical properties and information on longer chain chlorinated paraffins indicate that dermal absorption is predicted to be minimal. With respect to oral exposure, only limited studies on SCCP are available. Significant absorption (up to about 60% of the administered dose) does occur following oral administration. One study indicated that absorption is greater for SCCP with lower chlorination states. Absorbed CP have been shown to distribute preferentially to tissues of high metabolic activity and/or high rate of cell proliferation, following oral dosing. No attempts have been made to identify any metabolites of CP, although cytochrome P450 oxidation to CO_2 has been demonstrated. CP and/or their metabolites are excreted via exhaled air, urine and faeces, with up to approximately 60% of the administered dose being excreted in the air and urine in 12 hours. The only information on the toxicokinetics of SCCP in humans is from an in vitro study which demonstrated extremely poor absorption across skin samples (European Communities, 2000).
2.2	**Toxicology studies**	
2.2.1	**Acute toxicity**	There is no information available on the effects of acute exposure to SCCP in humans. However, the limited information available from animal studies clearly demonstrates that SCCP are of very low acute toxicity, with no toxicity occurring in rats following 1-hour exposure to a vapour or aerosol of 3300 mg/m^3 or with a dermal dose of 2.8 g/kg, and some signs of systemic toxicity with oral doses of up to 13 g/kg in rats and 27 g/kg in mice. A very high, unsubstantiated rabbit dermal LD_{50} of approximately 13 g/kg has been reported. The nature and degree of effects were independent from the degree of chlorination (European Communities, 2000). The acute toxicity of all CP is considered to be low with oral LD_{50} values for rats and mice being greater than 4 g/kg b.w. (Dover Chemical Corp., 1975; Birtley et al., 1980; Bucher et al., 1987). Signs of toxicity in rats, which were most evident

following oral administration of the shorter chain CP (doses greater than 4 g/kg b.w.) included piloerection, muscular incoordination, and urinary and fecal incontinence (Birdley et al., 1980; Government of Canada, 1993).

2.2.2 Short term toxicity

The liver and thyroid were identified as target organs in oral studies in rats and mice, however, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health. Other signs of toxicity, such as reduction in body weight gain and increase in kidney weight, were observed in several 14- and 90-days studies in rats and mice. NOAELs for effects considered relevant to human health of 100 and 1000 mg/kg bw/day were identified in rats and mice respectively (Norwegian notification).

2.2.3 Genotoxicity (including mutagenicity)

Overall, the data available (and a consideration of the generally unreactive nature of the SCCP), indicate that SCCP as a group are not mutagenic (Norwegian notification).

Available data are limited to the genotoxicity of the short chain CP. Although not mutagenic in bacterial assays in-vitro with or without metabolic activation (Birtley et al., 1980; NTP, 1986a), short chain CP have been clastogenic in in-vitro bioassays in the absence of metabolic activation (Myhr et al., 1990) and have also induced cell transformation in the majority of available in-vitro assays of this endpoint (ICI, 1982a). In two in-vivo studies, the complete reports of which were not available for this assessment, short chain CP did not induce dominant lethal mutations in rats or increase the frequency of chromosomal aberrations in bone marrow cells in rats (Serrone et al., 1987; Government of Canada, 1993).

2.2.4 Long term toxicity and carcinogenicity

In rodent studies the chlorinated paraffins tested produced toxicologically significant, dose-related increases in the incidence of several tumour types, e.g. in the liver, thyroid and kidney.

The substance is classified as carcinogenic in category 3, i.e. substances that cause concern for man owing to possible carcinogenic effects, but in respect of which the available information is not adequate for making a satisfactory assessment (Norwegian notification).

For SCCP, critical data relevant to both estimation of exposure of the general population in Canada and assessment of the weight of evidence for the mode of induction of specific tumours were identified following release of the first Priority Substances List (PSL1) assessment and prior to February 2001, although most of this information has been reported in incomplete published summary accounts or abstracts. These data suggest that several tumours observed in carcinogenicity bioassays in rats and mice exposed to SCCP are induced by modes of action either not relevant to humans (kidney tumours in male rats) or for which humans are likely less sensitive (in rats, liver tumours related to peroxisome proliferation and thyroid tumours related to thyroid-pituitary disruption). Complete documentation of available studies and consideration in additional investigations of the reversibility of precursor lesions in the absence of continued exposure is lacking. However, reported data on mode of induction of tumours in addition to the weight of evidence that SCCP are not DNA reactive are at least sufficient as a basis for consideration of a Tolerable Daily Intake (TDI) for non-cancer effects as protective for carcinogenicity for observed tumours. Upper-bounding estimates of daily intake of SCCP approach or exceed the TDI for these compounds, which, on the basis of available information, is likely also protective for potential carcinogenicity (UNEP/FAO/RC/CRC.10/6 section 2.4.2.1).

[The US NTP also conducted studies on SCCP in both rats and mice. In a 13-week study where rats were dosed with SCCP by gavage, a dose-related increase in relative liver weight was observed starting from the lowest dose of 313 mg/kg/day (NTP, 1986). The NTP also conducted a 13-week and a two year lifetime study on mice (NTP, 1986). In the -13-week study, a significantly increased relative liver weight was observed at doses of 250 mg/kg/day and higher. In the 2 years carcinogenicity study, doses of 125 and 250 mg/kg/day produced clinical signs of intoxication (decreased activity, prominent backbones, abnormal breathing) at both dose levels and survival was decreased in top dose females. Other effects included dose-related increases in hepatocellular carcinomas and adenomas, and in thyroid follicular cell carcinomas and adenomas.

Based on these studies, the International Agency for Research on Cancer determined in 1990 that there is sufficient evidence for the carcinogenicity (possibly carcinogenic

– group 2B) of the commercial chlorinated paraffin product tested, which is described as an average carbon-chain length C12 and average degree of chlorination 60% (IARC, 1990). Several mechanistic studies were conducted to understand the mechanisms of these tumours and whether they are relevant for human health (European Communities, 2000).

The Scientific Committee on Toxicity, Ecotoxicity and the Environment of the European Commission (CSTEE) reviewed a draft of the EU risk assessment for SCCP. The CSTEE concluded that:

"The liver and thyroid are target organs in repeated dose studies with rats and mice. The liver damage is associated with peroxisome proliferation, whereas the thyroid effects are correlated to altered thyroid hormone status and glucuronyl transferase induction. Humans would be much less sensitive to peroxisome proliferation and thyroid hormone perturbation than rats and mice."

In rats, neoplastic effects are seen in the liver, the thyroid (females) and the kidneys (males) as well as mononuclear cell leukaemia. There was poor survival in this experiment. In order to elucidate the mechanism underlying the renal tumorigenic effect, there were indications that a 58% chlorinated paraffin caused hyaline droplet formation in male rats, but this could not be confirmed by immunocytochemical techniques.

The CSTEE also found that the alveolar/bronchiolar carcinomas in male mice should not totally be discounted but acknowledged that "the control animals in this experiment did not show any evidence of lung tumours, whereas the historical control incidence was 5.8%."(CSTEE 1998). The final EU risk assessment (European Communities, 2000) noted that although there was an increase in alveolar/bronchiolar carcinomas in mice, the results were within historical control ranges and the controls had a greater incidence of adenomas of the lung than the treated animals. The EU concluded that rodent studies showed dose related increases in adenomas and carcinomas in the liver, thyroid, and kidney. They determined that there was insufficient evidence to conclude that the carcinogenicity observations in the liver and thyroid in mice and the benign tumours in the kidney of male rats were a male rat specific event and consequently the concern for humans could not be ruled out. SCCP are classified in the EU as a Carcinogen Category 3: R40 – Limited evidence of a carcinogenic effect, and are similarly classified as hazardous in Australia.

A recent study on the induction of renal tumours in male rats by SCCP (Warnasuriya et al. 2010, submitted by IPEN as an Annex E 2010 submission) indicates that the mechanism by which renal carcinogenic effects is induced by SCCP is complex and does not follow the classic profile of male-rat specific alpha-2-urinary globulin (α2u) nephropathy, i.e., accumulation of renal α2u and increase in regenerative cell proliferation. Though SCCP was found to bind to α2u, exposure to SCCP resulted in a down-regulation of α2u in the liver leading to no observed accumulation of renal α2u or increase in renal cell proliferation. However, the little α2u that was expressed in the liver appeared to accumulate in the kidney; this, plus the binding of SCCP to the α2u indicates that α2u nephropathy cannot be ruled out. It is hypothesized that peroxisome proliferation in the liver may be responsible for the suppression of α2u expression. As peroxisome proliferation is dose-dependent with SCCP, lower SCCP doses may result in less α2u expression, thus leading to greater α2u nephropathy and an inverse dose response in renal tumour incidence, as was observed in one study (NTP, 1986). Further study is needed to determine the exact mechanism of renal tumour induction by SCCP before it can be concluded that it is male-rat specific.

In conclusion, effects on the liver, thyroid, and kidney have been shown to occur in mammalian species exposed to short-chain chlorinated paraffins. The effects are manifested as organ weight increases and histological changes after exposure for weeks or months, but may turn into carcinomas and adenomas after chronic exposure. An overall NOAEL of 10 mg/kg/day can be derived from the 13-week studies. No NOAEL can be obtained from the chronic studies (POPRC draft risk profile, 2012).]

2.2.5 Effects on reproduction

There are no data available on fertility in animals; however, no changes were seen in the reproductive organs in rats and mice treated for 13 weeks with up to 5000 and 2000 mg/kg/day, respectively. In a study in rats chlorinated paraffins produced developmental effects at a dose which also caused maternal toxicity (2000 mg/kg), but no developmental effects at lower doses (500 mg/kg and below). For

developmental effects a NOAEL of 500 mg/kg/day has been established (Norwegian notification).

In a series of developmental studies conducted for the Chlorinated Paraffins Manufacturers Toxicology Testing Consortium, the number and location of viable and nonviable fetuses, early and late resorptions, the number of total implantations and corpora lutea, and the incidence of fetal malformations were examined following administration of a short chain CP (C10-13, 58% C1) by gavage in corn oil to pregnant Charles River rats on days 6 to 19 of gestation and pregnant Dutch Belted rabbits on days 6 to 27 of gestation. An increase in the incidence of adactyly and/or shortened digits in the offspring of rats exposed to a maternally toxic dose [2000 mg/kg bw/day by gavage in corn oil] (IRDC, 1982) and embryo- or feto-toxic effects at doses less than those that were toxic to the mothers were observed in rabbits exposed to 30 and 100 mg/kg b.w. (IRDC, 1983a; Government of Canada, 1993).

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

Available data are extremely limited on the potential neurotoxicity of short chain chlorinated paraffins. Following oral administration of a single dose (1 mg/kg b.w.) of a short chain CP (polychlorohexadecane) to 10-day-old male and female mice, there was no effect on muscarinic receptors, though it was suggested on the basis of an observed decrease in the Vmax for sodium-dependent choline uptake, that there was a presynaptic effect on the cholinergic system (Eriksson and Nordberg, 1986). There was a dose-related trend to decreased motor capacity in adult NMRI male mice administered a single dose of 30 to 300 mg/kg bw of a short chain CP (C10-13, 49% C1) intraperitoneally, which was statistically significant at the highest dose (Eriksson and Kihlstrom, 1985; Government of Canada, 1993).

2.2.7 Summary of mammalian toxicity and overall evaluation

- Limited information available from animal studies demonstrates that SCCP are of very low acute toxicity.
- For short-term toxicity, the liver and thyroid were identified as target organs in oral studies in rats and mice, however, the thyroid effects seen in rats and mice are considered unlikely to be relevant to human health.
- Regarding mutagenicity, the data available (and a consideration of the generally unreactive nature of the SCCP), indicate that SCCP as a group are not mutagenic.
- SCCP are suspected of causing cancer.
- Developmental effects of SCCP were observed in high dose groups in animal studies (2000 – 5000 mg/kg bw/day).
- Available data are extremely limited on the potential neurotoxicity of SCCP.

3 Human exposure/Risk evaluation

3.1 Food

Table 3.21 Concentration of combines short and intermediate chain length chlorinated paraffins (C_{10-20}) in human foodstuff (Campbell and McConnell, 1980)

Foodstuff class	No of samples analysed	Average concentration of C_{10-20} chlorinated paraffins (µg/kg)
Dairy products	13	300
Vegetable oils and derivatives	6	150
Fruit and vegetables	16	5
Beverages	6	ND

ND = not detected (detection limit = 50 µg/kg)
*Detected in approximately 70% of samples analysed
(European Communities, 2000)

Based on log K_{ow}'s of > 6, accumulation of CP via the food chain (i.e., biomagnification) could be significant (Thomann, 1989). In studies on uptake of various short chain (C10-13) chlorinated paraffins from food using rainbow trout (*Oncorhynchus mykiss*) and bleaks (*Alburnus alburnus*), BAFs ranged from 2 to 41 on a wet weight (w.w.) basis (Lombardo et al., 1975; Bengtsson and Ofstad, 1982), indicating that biomagnification could occur in the environment (Government of Canada, 1993).

In a market basket survey (KAN-DO Office and Pesticides Team, 1995) [3] of 234 ready to-eat foods, which represented approximately 5000 food types in American diets, "Chlorowax 500C" was detected once, in enriched white bread, at a concentration of 0.13 µg/g. Food items were screened by gas or liquid chromatography using ion-selective detectors. Findings were confirmed by unspecified analysis (Government of Canada, 2003).

Upper-bound estimates of intake of SCCP were calculated for the general Canadian population. For each age group in the Canadian population, virtually all of the estimated intake is from food. The upper-bound estimated intake of breast-fed infants was 1.7 µg/kg bw per day, and that of formula-fed infants was 0.01 µg/kg bw per day. For the remaining age groups, intakes ranged from 5.1 µg/kg bw per day for adults over 60 years of age to 26.0 µg/kg bw per day for infants who were not formula fed (i.e., those being introduced to solid foods).

Canadian data incorporated within this estimate include high-confidence values in fish (whole carp determined by GC/ECNI-HRMS) and data on breast milk, for which details of sampling and analysis were not reported. Estimated intake of SCCP in fish represents up to 58% of the total daily intake. The intake from dairy products, which accounts for 89.9% of the intake of infants not formula fed, is based upon limited sampling and analysis — considered semiquantitative only — of dairy products in the United Kingdom, reported in 1980. Probably the most representative estimates of intake are those from cereals, which are based upon data reported in an American market basket survey, carried out from 1982 to 1991; however, intake from this foodstuff constitutes <0.1% of total estimated intake, and analytical methods were not specified.

Intake of SCCP by a potentially higher-exposure subgroup of Inuit for whom the primary source of food is subsistence hunting and fishing (Kuhnlein, 1989; Kinloch et al., 1992) was also estimated, based on data on concentrations of SCCP in blubber from marine mammals in Canada (Tomy et al. 2000) and less specific data (including both SCCP and MCCP) for terrestrial and marine mammals from Sweden (Jansson et al., 1993). On the basis of these data, the estimated intake of an Inuit adult, namely 1.47 µg/kg bw per day, is well within the range of values estimated above for the general population (see supporting documentation) (Government of Canada, 2003).

3.2 Air

Tomy (1997) determined SCCP (C10–13, 60–70% chlorine) in 24-hour air samples collected daily during a 4-month period in the summer of 1990 in Egbert, Ontario, a "rural site northwest of Toronto," by HRGC/ECNI-HRMS (Muir et al., 1999). Concentrations ranged from 65 to 924 pg/m^3. Although a summary statistic of 543 pg/m^3 was reported, it was not specified whether this was a mean or median value. Egbert has also been reported to be near an "industrialized area" (Muir et al., 2000). Lower concentrations of SCCP have been identified at other sites in Canada (Halsall et al., 1998; Stern et al., 1998; Bidleman et al., 1999, 2000, 2001; Muir et al., 2001) (Government of Canada, 2003).

3.3 Water

Data on concentrations of SCCP in drinking water in Canada or elsewhere were not identified. The maximum concentration of SCCP (C10–13, 50–70% chlorine) in the Red River, at a site remote from industrialized areas, was 0.05 µg/L (Tomy, 1997) (Government of Canada, 2003).

3.4 Occupational exposure

At the exposure levels presented (negligible up to 63 mg/m^3), the only effects that are likely to be of concern are those arising from repeated exposures (doses), i.e. general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, in all but one case, the margin of safety is considered to be adequate, that is at least two orders of magnitude. While it is important not to read too much into simple ratios, this does suggest that, in general, the use of the substance is appropriately controlled. While certain uses imply a narrower margin of safety, these are not considered to be a cause for concern (European Communities, 2000)

3.5 Medical data contributing to regulatory decision

-

3.6	**Public exposure**	The only effects that are likely to be of concern are those arising from repeated exposures (doses), that is general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, the margins of safety are well over three orders of magnitude and, given the conservative nature of the exposure calculations, in all probability considerably more. While it is important not to read too much into simple ratios, this does suggest that the use of the substance poses no significant risk for consumers (European Communities, 2000).
3.7	**Summary-overall risk evaluation**	The only effects that are likely to be of concern are those arising from repeated exposures (doses), that is general toxicity, kidney carcinogenicity and developmental effects. When compared to the relevant NOAELs, the margins of safety are well over three orders of magnitude and, given the conservative nature of the exposure calculations, in all probability considerably more. While it is important not to read too much into simple ratios, this does suggest that the use of the substance poses no significant risk for both workers and consumers (European Communities, 2000). Available data relevant to consideration of the weight of evidence for proposed modes of induction of liver, kidney and thyroid tumours associated with exposure to SCCP, although limited, are suggestive that tolerable intakes that protect for non-neoplastic precursor effects will likely also be protective for cancer. However, owing principally to limited investigation of aspects such as recovery and inadequate documentation of relevant studies, there is considerable uncertainty in drawing this conclusion, particularly for the thyroid tumours (Government of Canada, 2008).

4	**Environmental fate and effects**	
4.1	**Fate**	In the EU risk assessment, it was found that some major characteristics of C10-13 chloroalkanes are relevant for the assessment of exposure to the environment: the C10-13 chloroalkanes are not hydrolysed in water; are not readily or inherently biodegradable; have a high log Kow value (4.4 - 8) and have an estimated atmospheric half-life of 1.9 - 7.2 days. The high log Kow values indicate a high potential for bioaccumulation, strong adsorption to sludge and sediments and very low mobility in soil. High bioconcentration factors have been reported with a variety of freshwater and marine organisms (ranging from 1000 to 50000 for the whole organism, with higher values for individual tissues) (OSPAR, 2009). Few data are available on the environmental fate of CP because of the complex nature of the mixtures and difficulties in measuring low levels. Based on general patterns of behaviour of hydrophobic organics in the environment, it is likely that CP are fairly immobile, remain adsorbed onto soil or sediment particles, and are slowly degraded. In the natural environment, CP are generally stable, but degradation is possible by micro-organisms (Madeley and Birtley, 1980). The ability of aerobic micro-organisms to oxidize a range of CP depends on the previous acclimatization of the microbes, the chain length, and the degree of chlorination of the CP. Short and medium chain CP (i.e. C10-20) are degraded most rapidly. The longer the carbon chain and the higher the chlorine content, the less chlorine is released (Omori et al., 1987). Few data have been identified on the mobility and transport of CP residues from sites of manufacturing, use, or disposal. However, some of the calculated Henry's Law constants for CP are similar to those for chlorinated aliphatic pesticides, such as toxaphene, chlordane, and aldrin (Sunito et al., 1988), which are known to be transported in the atmosphere. Airborne dispersion of CP has been found in the United Kingdom and Sweden where monitoring data indicate widespread levels of low contamination in water, sediments, aquatic and terrestrial biota, and even commercial foods (Campbell and McConnell, 1980; Jansson et al., 1993). Chlorinated paraffins are generally considered to be persistent. Hydrolysis, oxidation, and photolysis with visible or near ultraviolet radiation are insignificant routes of transformation at ambient temperatures. No experimental data are available on the fate of any CP that volatilize to the atmosphere. However, it may be assumed that any volatilized CP would be subject to attack by hydroxyl radicals in the troposphere. Using the method of Atkinson (1986) for estimating the rate constant for reaction of

chlorinated paraffins with hydroxyl radicals, the likely tropospheric half-life is a few days under summer conditions.
While data indicate a potential for bioaccumulation, few bioconcentration factors (BCFs) or biomagnification factors (BAFs) have been experimentally determined. The uptake and accumulation of CP in fish from water and food appear to be inversely proportional to molecular weight, i.e., CP with short chain length and low chlorine content are taken up most rapidly. Similarly, depuration is slowest for highly chlorinated forms. Measurement of BCFs and BAFs is difficult due to the low water solubility of these substances, and subsequent slow uptake rates requiring long exposure periods to achieve steady-state equilibrium. In several of the reviewed tests, it was unclear whether steady-state had been achieved. Reported bioconcentration factors vary dramatically between different CP and between species, ranging from 0.007 to 139000 (Sundstrom and Renberg, 1985). The highest bioconcentration factor, which was observed for mussels (Renberg et al., 1986), was reported at a much lower concentration of chlorinated paraffins in water than that in most other studies. Observations for dioxins and furans have been similar, with Cook et al. (1991) reporting much higher BCFs when aquatic
species were exposed to concentrations of pg/L rather than ng/L.
Based on log Kow's of >6, accumulation of CP via the food chain (i.e., biomagnification) could be significant (Thomann, 1989). In studies on uptake of various short chain (C10-13) chlorinated paraffins from food using rainbow trout (*Oncorhynchus mykiss*) and bleaks (*Alburnus alburnus*), BAFs ranged from 2 to 41 on a wet weight (w.w.) basis (Lombardo et al., 1975; Bengtsson and Ofstad, 1982), indicating that biomagnification could occur in the environment (Government of Canada, 1993).

4.1.1 Soil

Predicted concentrations of short chain length chlorinated paraffins in soil have been calculated using EUSES (see Section 3.1.1.2). The concentrations obtained in the regional model were 11.5 µg/kg wet wt in natural/industrial soil and 10.8 mg/kg wet wt in agricultural soil. Similarly the levels calculated using the continental model were 4.6 µg/kg wet wt in natural/industrial soil and 0.95 mg/kg wet wt in agricultural soil respectively. The high level predicted in agricultural soil is mainly due to the assumption that high levels of chlorinated paraffins will be present in sewage sludge applied to the soil.
Short chain length chlorinated paraffins have been measured at levels of 47-65 mg/kg dry weight in sewage sludge from a waste water treatment plant in Germany that received both industrial and domestic wastewater (see Section 3.1.1.3) (European Communities, 2000).

Concentrations of SCCP in soil in Canada or elsewhere were not identified. The concentrations in surface sediment in harbours in Lake Ontario ranged from 5.9 to 290 ng/g dry weight (Muir et al., 2001). Analyses were by HRGC/ECNI-HRMS (Government of Canada, 2003).

4.1.2 Water

Short chain length chlorinated paraffins are likely to adsorb strongly onto suspended sediments. When interpreting the measured levels of chlorinated paraffins in water it is important to try to distinguish between levels that refer to chlorinated paraffins in the dissolved phase and those that refer to chlorinated paraffin adsorbed onto suspended matter (European Communities, 2000).

Concentrations of SCCP in surface water, sediment, sewage sludge up to 2001
Monitoring data from the EU Risk Assessment Report (1999) and from Organohalogen Compounds, Volume 47 (2000) are summarised here:
Levels of 0.12 - 1.45 µg/L have been measured in surface water in rivers from industrial areas in the United Kingdom in the year 1986;

- Levels of 0.50 - 1.2 µg/L and 0.05 - 0.12 µg/L have been measured in two rivers in Germany in the years 1987 and 1994, respectively. These values include sites downstream from a chlorinated paraffins production plant;
- Levels of 17 - 83 µg/kg dry weight in sediments have been measured in rivers in Germany in 1994. These values also includes sites downstream from a chlorinated paraffins production plant;
- Levels of 47 - 65 µg/g in sewage sludge have been measured near a metal working plant in Germany. Further levels around 0.12 µg/L in the run-off

water from the sewage plant into a nearby river, and of 0.08 and 0.07 µg/L in the river water, up and downstream from the metal working plant have been measured in the years 1991 to 1993;

- Levels of 18 - 275 µg/kg dry weight in surface sediments have been measured in three lakes in Canada;
- Levels of 0.0073 - 0.29 µg/g in surface sediment have been measured in harbour areas along Lake Ontario;
- Average levels around 1.8 µg/g have been measured in sediment of the Detroit River at Lake Eire in Canada;
- Levels of 0.06 - 0.448 µg/L have been measured in final effluent from sewage treatment plants in southern Ontario in Canada in 1998;
- Levels of around 0.0045 µg/g dry weight have been measured in sediment in Lake Hazen on Ellesmere Island in the Arctic;
- Estimates of SCCP in waters in non-industrial areas compared to marine waters and industrial areas in the United Kingdom were 0.1 - 0.3, 0.1 - 1 and 0.1 - 2 µg/L, respectively.

These data were estimated from analytical values for all chlorinated paraffins in the range C10-C20 (data published in 1980).

Monitoring data of SCCP in sediments, water, digested sludge and soil published after 2001

- In general, Baltic Sea sediments were more contaminated with Chloroparaffins (CP) than North Sea sediments. The concentrations of SCCP in sediments from the North Sea varied between 5 to 112 ng/g dw and in sediments from the Baltic Sea between 116 to 377 ng/g dw. The samples were collected between August 2001 and May 2003 (Huttig and Oehme, 2005);
- The concentrations of SCCP in surface sediments collected during 1998 in Lake Ontario in North America were on average 49 ng/g dw with the highest concentrations ranging from 147 to 410 ng/g dw (Marvin *et al.* 2003). The highest concentrations were found in the most industrialised areas. Core samples from a polluted site in the Niagara Basin showed a decreasing trend of accumulation of SCCP with the highest peak during the 1970s of about 700 - 800 ng/g dw. However at a background site in Lake Ontario there was still a slight increase in accumulation of SCCP (Marvin *et al.* 2003);
- SCCP and MCCP (medium chain chlorinated paraffins) in samples from the UNITED KINGDOM collected 1983 to 1988 showed concentration levels in sediment of <0.2 - 65.1 mg/kg dw, in water <0.1 - 1.7 µg/L, in digested sewage 1.8 - 93.1 mg/kg dw and in soil <0.1 mg/kg dw (Nicholls *et al.* 2001). These sampling sites were chosen on the basis of target specific industries;
- Sediments in 11 Czech rivers were collected during 2003 and 2004, were analysed for SCCP. Concentrations of SCCP were between 6 to 397 ng/g dw. The highest concentration occurred close to a chemical and electro engineering industry (Pribylová *et al.*, 2006);
- The concentrations of SCCP in sediments from the Czech Republic varied in the Kosetice area between 24 to 46 ng/g dw, in the Zlin area 16 to 181 ng/g dw and in the Beroun area from 5 to 22 ng/g dw (Stejnarova *et al.* 2005). The Kosetice area is considered to be a background area, the Zlin area is a typical industrial region with rubber, tanning and textile industries and the Beroun area represents the cement and machinery industries;
- Sediments from Lake Mälaren in Sweden were collected close to an urban area,
- Stockholm. The concentrations of SCCP in the sediments varied between 170 to
- 3300 ng/g dw in samples collected at sites close to the city and between 8 - 63 ng/g dw at urban background sites (Sternbeck *et al.*, 2003);
- Sediment samples were collected in Norway and analysed for SCCP and the results varies between 5.8 to 1300 ng/g dw. High concentrations were found in *e.g.* Trondheim harbour, while Tromsö harbour showed as low concentrations as 5.8 ng/g dw (Fjeld *et al.*2004) (OSPAR, 2009).

SCCP were detected in surface waters in Canada and the United Kingdom. Low levels of dissolved total (C10-13) SCCP were measured in western Lake Ontario between 1999 and 2004 (Muir et al. 2001, Houde et al. 2006). The concentration of

total SCCP was 1.75 ng/L in 1999. Concentrations of total SCCP ranged from 0.606 – 1.935 ng/L over the 2000 – 2004 sampling period. Concentrations were generally greater in western Lake Ontario, likely due to the proximity of large urban areas (Houde et al. 2006). SCCP concentrations of 30 ± 14 ng/L were measured in the Red River in Selkirk, Manitoba, over a 6-month period in 1995 (Tomy 1997) (Government of Canada, 2008).

4.1.3 Air

Predicted concentrations of short chain length chlorinated paraffins in air have been calculated using EUSES for the local, regional and continental scenarios (see Section 3.1.1.2). The estimated regional air concentration is 11.6 ng/m^3. It is thought that direct emissions of chlorinated paraffin vapour to the atmosphere from local sources are likely to be very low (most emissions will be to water), therefore the PEClocal (air) is likely to be very low. The predicted concentrations in air from EUSES are <2.79 ng/m^3 for most local scenarios, which are lower than the regional background concentration of 11.6 ng/m^3. The one exception to this is the leather use (scenario B), where a direct releases to air give an estimated concentration during an emission event of 138 ng/m^3 and an annual average PEClocal (air) of 17.8 ng/m^3. In the regional and continental model, very little direct input into the atmosphere was assumed and so the levels reflect the small, but measurable volatility of the substance (see also Section 3.1.0.7).

No measured data appear to exist on the air levels of short chain length chlorinated paraffins (European Communities, 2000).

SCCP were detected in air in Canada, United Kingdom and Norway. They have also been detected in arctic air and in air of other remote areas (Section 4.2.1). Concentrations of SCCP in air samples collected at Egbert, Ontario, Canada, in 1990 ranged from 65 to 924 pg/m^3 (Tomy 1997; Tomy et. al. 1998a). Concentrations of SCCP over Lake Ontario in 1999 and 2000 ranged from 120 to 1,510 pg/m^3 (Muir et al. 2001).

No atmospheric concentration data are available for MCCP and LCCP, either in Canada or elsewhere (Government of Canada, 2008).

4.1.4 Bioconcentration

Short chain length chlorinated paraffins have been shown to bioconcentrate to a large extent in fish and molluscs. Bioconcentration factors from various studies ranged from 574-5300 L/kg for fish (whole fish BCF) and from 5785-40900 L/kg for mussel (European Communities, 2000).

See also sections 4.1 and 4.2.2

4.1.5 Persistence

Based on general patterns of behaviour of hydrophobic organics in the environment, it is likely that CP are fairly immobile, remain adsorbed onto soil or sediment particles, and are slowly degraded (Government of Canada, 1993).

See also section 4.1

[Summary of Persistence

SCCP are sufficiently persistent in air for long range transport to occur. SCCP appear to be hydrolytically stable. While there is evidence that low chlorinated SCCP can readily degrade in water under enhanced conditions, the ecological relevance of the test results is not known. There is insufficient information to conclude on the persistence of higher chlorinated SCCP in water. There is also insufficient information on their persistence in soil. Overall, SCCP are considered to meet the criteria for persistence in Annex D (POPRC, 2012).]

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

An avian reproduction study using Mallard ducks has been carried out with a C10-12, 58% Cl chlorinated paraffin. The study was a 22 week feeding study, including a 9 week pre-egg-laying period without photostimulation, a 3 week pre-egg-laying period with photostimulation and a 10 week egg laying period with photostimulation. Slight effects on reproduction were seen at 1000 ppm in diet. Therefore the NOAEC is 166 ppm in diet (166 mg/kg food) (European Communities, 2000).

Very limited information is available on SCCP concentrations in tissues of terrestrial wildlife. In Sweden, Jansson et al. (1993) reported CP concentrations (unspecified chain length) in rabbit (Revingeshed, Skåne), moose (Grismsö, Västmanland), reindeer (Ottsjö, Jaämtland) and osprey (from various regions in Sweden) to be 2.9, 4.4, 0.14 and 0.53 mg/kg lipid wt., respectively. Nicholls et al. (2001) reported the

concentrations of SCCP and MCCP in earthworms residing in fields on which sludge had been applied ranging from <0.1 to 0.7 mg/kg dry wt. in the United Kingdom in the summer of 1998.

Campbell and McConnell (1980a) determined levels of C10–20 CP in birds in the United Kingdom. The C10–20 levels were likely to be dominated by contributions from the SCCP and MCCP. Concentrations of C10–20 CP ranged from 0.1 to 1.2 mg/kg weight wt. in liver of birds and from <0.05 to >6 mg/kg in seabird eggs. Concentrations of C20–30 CP ranged from not detected to 1.5 mg/kg weight wt. in liver of birds and from <0.05 to 1 mg/kg in seabird eggs. Reth et al. (2006) quantified SCCP in liver and muscle from the seabirds, little auk (*Alle alle*) and kittiwake (*Rissa tridactyla*) collected at Bear Island (European Arctic). Concentrations between 0.005 and 0.088 mg/kg wet weight were measured. Reth et al. (2006) determined the concentration of C14-15 MCCP in seabirds from the European Arctic.

Concentrations ranged from 0.005 to 0.370 mg/kg wet wt (Government of Canada, 2008).

4.2.2 Aquatic species

Fish

Short chain length chlorinated paraffins appear to be of low acute toxicity to fish with 48 and 96 hour LC50s in excess of 100 mg/L. However, it should be noted that such values are well in excess of the solubility of this group of compounds. Chronic toxicity values include a 60 day LC50 at 0.34 mg/L and no observed effect concentrations of <0.040 and 0.28 mg/L for rainbow trout and sheepshead minnow respectively (European Communities, 2000).

Aquatic invertebrates

Twenty four hour EC50s for daphnids range from 0.3 to 11.1 mg/L with acute no observed effect concentrations ranging from 0.06 to 2 mg/L. There appears to be no clear pattern with regard to the effects of the carrier substance or the degree of chlorination on the acute toxicity of short chain length paraffins to *D. magna*. In 21day tests EC50s ranged from 0.101 to 0.228 mg/L; NOECs ranged from 0.005 to 0.05 mg/L.

The NOEC of 0.005 mg/L for the 58% chlorinated short chain length paraffin means that this species is the most sensitive aquatic species tested.

The second instar of the midge *Chironomus tentans* was exposed to a C10-12, 58% chlorinated paraffin at levels ranging from 18 to 162 µg/L for 48 hours. This caused no adverse effects on the test organism. The use of this paraffin over the whole 49 day life cycle at concentrations of 61 to 394 µg/L also gave no significant response except in halting adult emergence at 121 and 394 µg/L. This led to a maximum acceptable toxicant concentration (MATC) for this paraffin of between 78 and 121 µg/L, with a geometric estimated value for the MATC of 97 µg/L. The NOEC for this study is 61 µg/L (E & G Bionomics, 1983).

Thompson and Madeley (1983d) studied the toxicity of a 58% chlorinated short chain length paraffin to the mysid shrimp *Mysidopsis bahia* and found the 96 hour LC50 to be between 14.1 and 15.5 µg/L, with the lowest concentration causing a significant mortality at 13.7 µg/L. The chronic toxicity of this compound was studied in 28 day exposures to concentrations of 0.6, 1.2, 2.4, 3.8 and 7.3 µg/L. Significant mortalities were observed in some of the groups during the test but these were not treatment related. There was no treatment-related effect on reproductive rate (offspring per female) or growth over the 28 day test period. A no effect level was determined as 7.3 µg/L.

Madeley and Thompson (1983) studied the toxicity of the 58% chlorinated short chain length paraffin (C10-14) to the mussel *Mytilus edulis* over a period of 60 days. Tests were carried out at measured concentrations of 0.013, 0.044, 0.071, 0.13 and 0.93 mg/L (nominal concentrations were 0.018, 0.056, 0.1, 0.32 and 3.2 mg/L). There was significant mortality at 0.071, 0.13 and 0.93 mg/L with LT50s of 59.3, 39.7 and 26.7 days for the three exposure concentrations respectively. There was no significant mortality observed at concentrations of 0.013 and 0.044 mg/L; reductions in filtration rate were reported but these were not measured quantitatively. The 60-day LC50 was estimated to be 0.074 mg/L based on measured concentrations.

A further study on mussels *Mytilus edulis* using a 58% chlorinated short chain length chlorinated paraffin has been carried out by Thompson and Shillabeer (1993). The study was carried out as a follow up to a bioaccumulation study and only two exposure concentrations were used.

Groups of 30 mussels were exposed to measured concentrations of 2.3 µg/L or 9.3 µg/L in seawater for 12 weeks in a flow-through system. No mortalities were

seen in any of the exposure groups or controls, but growth (as assessed by increase in shell length and tissue weight) was significantly reduced in the group exposed to 9.3 µg/L. No significant effects were seen in the group exposed to 2.3 µg/L (European Communities, 2000).

Algae

Ninety-six hour EC50s range from 0.043 to 3.7 mg/L with the marine alga *Skeletonema costatum* appearing to be more sensitive to short chain length paraffins than the freshwater alga *Selenastrum capricornutum*. A NOEC of 12.1 µg/L was reported in the study on *S. costatum*. It should be noted that the EC50 values given for *Selenastrum* exceeded the highest mean measured concentrations of the test substance; they are, therefore, extrapolated values.

Further, the toxic effects seen with the marine alga were transient, with no effects being seen at any concentration after 7 days exposure (European Communities, 2000).

Microorganisms

Short chain length chlorinated paraffins appear to be of low toxicity to the microorganisms tested. In anaerobic microorganisms, Madeley et al. (1983b) used measurements of gas production and its inhibition to assess the toxicity of a short chain length C10-12, 58% chlorinated paraffin to the anaerobic sludge digestion process. This study showed that significant (>10%) inhibition of gas production occurred when chlorinated paraffin concentrations of 3.2, 5.6 and 10% on digester volatile suspended solids were employed.

These effects were observed on the first 3 to 4 days of the experiment, after which, gas production recovered to normal levels until day 10 when the study was terminated. It was concluded that the compound tested caused transient partial inhibition of gas production with rapid recovery and no longer-term effects (European Communities, 2000).

Concentrations of SCCP in Biota up to 2001

- Mussels were collected up and downstream from a chlorinated paraffin manufacturing site in the United States. Measured levels of SCCP ranged between 7 - 280 µg/kg;
- High levels of SCCP have been measured in different marine mammals in the Arctic, such as seal from Iceland and walrus from Western Greenland. The measured concentrations of SCCP were 526 and 426 µg/kg in blubber, respectively;
- On a lipid basis, average levels of 13 µg/kg of SCCP have been measured in breast milk from Inuit women living in communities on the Hudson Strait in Northern Quebec;
- Levels of SCCP of 370 - 1400 µg/kg have been measured in beluga blubber from the St. Lawrence River in Canada;
- Average levels of SCCP of 630 µg/kg, 200 µg/kg, 320 µg/kg and 460 g/kg have been measured in blubber from male beluga collected in different Arctic places; Hendrickson Island, Arivat (Western Hudson Bay), Sanikiluaq (Belcher Island area in southern Hudson Bay) and in Pangnirtung (south eastern Baffin Island), respectively.
- On a lipid basis, levels of around 1500 µg/kg chlorinated paraffins (C6-C16) have been measured in herring (muscle), in the Bothnian Sea, in the Baltic Sea and in Skagerrak in Sweden in the years 1986 and 1987;
- High concentrations of chlorinated paraffins (C6-C16) have also been measured in rabbit and moose (2900 and 4400 µg/kg, respectively on a lipid basis) in Sweden in 1986;
- On a lipid basis, levels of around 130 and 280 µg/kg chlorinated paraffins (C6-C16), respectively, have been measured in ringed seal blubber from Kongsfjorden, Svalbard in 1981 and in grey seal blubber from the Baltic Sea during 1979 - 85;
- On a lipid basis, levels of chlorinated paraffins (C6-C16) of around 1000 µg/kg and 570 µg/kg, respectively, have been measured in whitefish muscle in Lake Storvindeln, Lapland, in Sweden and in Arctic char muscle in Lake Vättern, central Sweden in 1986 and 1987;

- On a lipid basis, levels of chlorinated paraffins (C6-C16) of around 140 µg/kg and 530 µg/kg, respectively, have been measured in reindeer suet and in osprey muscle in Sweden in 1986;
- Levels of chlorinated paraffins (C10-C20) up to 200 µg/kg in fish, 100 - 12 000 µg/kg in mussels, levels in mussels above 200 µg/kg have been measured in the Wyre Estuary close to a paraffinic production site, 50 - 2000 µg/kg have been found in seabirds (eggs), 100 - 1200 µg/kg in heron and guillemot, 200 - 900 µg/kg in herring gull, 50 - 200 µg/kg in sheep close to a chlorinated paraffin production plant and 40 - 100 µg/kg in grey seal have been found in the United Kingdom (data published in year 1980). All these values were estimated from analytical values for all chlorinated paraffins in the range C10 to C20;
- Stern et al. (1998) noted that the Arctic formula group profiles showed higher proportions of the lower chlorinated congeners (Cl5-Cl7), suggesting that the major source of contamination to the Arctic is via long range atmospheric transport.

Monitoring data of SCCP in Biota published after 2001

- In liver samples of little alks collected in the European Arctic SCCP levels of 5 - 88 ng/g ww were found (Reth et al. 2006). The range for SCCP in cod varied from 11 to 70 ng/g ww, and in Arctic char from 7 to 27 ng/g ww;
- Fish from the North Sea and the Baltic Sea were collected during 2002; cod, flounder and North Sea dab. In the Baltic Sea the concentration levels of SCCP varied between 19 and 221 ng/g ww, and in the North Sea the levels varied between 26 and 286 ng/g ww. The congener patterns in the samples from the Baltic Sea were similar to commercial SCCP mixtures and C13 were the most abundant, while the North Sea samples had a higher abundance of C10 (Reth et al. 2005);
- In ringed seals from Pangnirtung and Eureka in the Canadian Arctic, levels of SCCP of 95 and 527 ng/g ww were found, respectively (Braune et al. 2005);
- The concentrations of SCCP and MCCP in biota samples collected during 1983 to 1988 in UNITED KINGDOM were in fish <0.1 - 5.2 mg/kg ww, in benthos <0.05 - 0.8 mg/kg ww and in earthworms <0.1 - 1.7 mg/kg ww (Nicholls et al. 2001);
(OSPAR, 2009)

Pelagic aquatic organisms

The lowest toxic effect level identified for a pelagic freshwater aquatic species is 8900 ng/L, which is the 21-day chronic LOEC for *Daphnia magna* (Thompson and Madeley 1983a). The effect was for mortality of the offspring. The NOEC is 5000 ng/L.

Benthic organisms

A valid measurement endpoint was not available for a sediment-dwelling invertebrate. As a result, an equilibrium partitioning approach (Di Toro et al. 1991) using the most sensitive chronic measurement endpoint identified for a pelagic freshwater invertebrate aquatic species (8900 ng/L) was used to estimate the toxicity to benthic organisms. The LOECbenthic was estimated to be 35.5 mg/kg dry wt. for sediment containing 2% organic carbon (Environment Canada, 2008) (Government of Canada, 2008).

4.2.3 Honeybees and other arthropods

No data available.

4.2.4 Earthworms

Soil-dwelling organisms

Bezchlebová et al. (2007) investigated the effects of SCCP on the survival and reproduction of five species of soil organisms (*Fosomia candida, Eisenia fetida, Enchytraeus albidus, Enchytraeus crypticus*, and *Caenorhabditis elegans*). All tests were performed following international methods, using an OECD artificial soil (70% sand, 20% clay, 10% peat) with an organic carbon content of approximately 2.7%. *Folsomia candida* (Collembola) was identified as the most sensitive organism, with an LC_{50} value for adult survival and EC_{50} and EC_{10} values for reproduction of 5733, 1230, and 660 mg/kg dry wt. (nominal), respectively. The soil CTV for SCCP is 660 mg/kg dry wt (Government of Canada, 2008).

In the EU-RAR, there are no studies available on plants, earthworms or other soil-dwelling organisms. In the absence of any ecotoxicological data for soil-dwelling organisms, the PNEC may provisionally be calculated using the equilibrium partitioning method with the PNEC for aquatic organisms and the soil/water partition coefficient.
PNECsoil = Ksoil-water /Psoil · PNECaquatic organisms · 1000 where K soil-water = soil - water partition coefficient = 2736 for a log K_{ow} of 6. Psoil = density of soil = 1700 kg/m^3
However, the ingestion of the soil-bound substance by soil-dwelling organisms may not be sufficiently explained by this relationship for substances with a log Kow greater than 5. The Technical Guidance Document suggests that the PEC/PNEC ratio is increased by a factor of 10 to take account of ingestion.
The reported log Kow for short chain length chlorinated paraffins range from 4.39-8.69 and so the equilibrium partitioning method is not really applicable to these substances. However, in the absence of any other data a tentative PNEC for soil can be calculated assuming a K soil-water of 2736 m^3/m^3. This gives a PNEC for soil of 0.80 mg/kg wet weight.
It must be borne in mind that data obtained for aquatic organisms cannot replace data for terrestrial organisms because the effects on aquatic species can only be considered as effects on soil-dwelling organisms which are exposed exclusively to the interstitial water of the soil (European Communities, 2000).

4.2.5 Soil microorganisms See section 4.2.4

4.2.6 Terrestrial plants See section 4.2.4

5 Environmental Exposure/Risk Evaluation

5.1 Terrestrial vertebrates In a 13-week oral (gavage) rat study by IRDC (1984), increases in liver and kidney weight and hypertrophy of the liver and thyroid occurred at doses of 100 mg/kg bw per day. This value was the most sensitive LOAEL for mammals. Interspecies scaling using data for a typical adult otter was used to extrapolate to a food concentration for this species. This resulted in a critical toxicity value (CTV) of 1000 mg/kg food (Environment Canada, 2008).

5.2 Aquatic species A PNEC of 0.5 µg/L has been derived for the freshwater aquatic compartment.
The PEClocal for fresh surface water depends on the release source. The worst case ratios are summarised in Table 3.31.

Table 3.31 PEC/PNEC ratios for the aquatic compartment

Scenario	PEC/PNEC ratio
PEC_{local} Production (2 sites)	**< 0.72 – site specific** **< 0.86 – site specific**
PEC_{local} Metal working (formulation)	**8.6**
PEC_{local} Metal working (use)	**2.8 or 10**
PEC_{local} Rubber formulations	**< 0.68**
PEC_{local} Paints and sealing compounds	**Neglible**
PEC_{local} Leather (formulation: scenario A) **PEC_{local} Leather (formulation: scenario B)** **PEC_{local} Leater (use: scenario B)**	**[124]** **154** **154**
PEC_{local} Textile applications	**Negligible**
$PEC_{regional}$	**0.66**
$PEC_{continental}$	**0.066**

The PEC/PNEC ratios indicate a significant risk to freshwater aquatic organisms from some local sources (European Communities, 2000).

5.3 Honey bees *no data*

5.4	**Earthworms**	Based on the calculated PEC/PNEC ratio for soil-dwelling organisms (see section 4.2.4), the following was concluded in the EU-RAR: For production sites (site specific data), and use in rubber formulations, paints and sealing compounds and textile applications: ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already. For all other scenarios: i) There is a need for further information and/or testing The need for further information and/or testing should be re-evaluated once the outcome of the risk reduction measures recommended for surface water are known (European Communities, 2000).
5.5	**Soil microorganisms**	
5.6	**Summary – overall risk evaluation**	The use of short chain length chlorinated paraffins in sealants, rubber, back coating of textiles and paints is not thought to present a risk to the environment. Secondary poisoning is not thought to be of concern, except for leather treatment formulation and use and possibly for use in metal finishing. No risks to the function of sewage treatment plants were identified from either production or any use. For the atmospheric compartment, neither biotic nor abiotic effects are considered likely to occur as a result of production or any use. Short chain length chlorinated paraffins have been raised as a possible concern with regard to long range atmospheric transport. This area is currently being discussed within the appropriate international fora. The use of short chain length chlorinated paraffins in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures. Possible risks to sediment-dwelling organisms were identified as a result of production of short chain length chlorinated paraffins, formulation and use of metal cutting fluids and formulation and use of leather finishing products, use in rubber formulations, and at a regional level. There is a possible risk to soil-dwelling organisms in agricultural soils at a local level (for metal working fluid formulation and use, and leather finishing formulation and use) and at a regional level due to spreading of sewage sludge. Further information for the soil and sediment compartments could be gathered to clarify the risk. However, risk reduction methods should be considered for metal working since further information (either exposure or aquatic toxicity) is unlikely to change significantly the PEC/PNEC ratios calculated for aquatic organisms. Based on the available data, a risk to aquatic organisms cannot be excluded for leather finishing applications either and so risk reduction measures should also be considered for this use (European Communities, 2000). In the EU risk assessment, it was found that some major characteristics of C10-13 chloroalkanes are relevant for the assessment of exposure to the environment: the C10-13 chloroalkanes are not hydrolysed in water; are not readily or inherently biodegradable; have a high log Kow value (4.4 - 8) and have an estimated atmospheric half-life of 1.9 - 7.2 days. The high log Kow values indicate a high potential for bioaccumulation, strong adsorption to sludge and sediments and very low mobility in soil. High bioconcentration factors have been reported with a variety of freshwater and marine organisms (ranging from 1000 to 50000 for the whole organism, with high values for individual tissues). SCCP have been raised as a concern with regard to long range transport. This is currently being discussed within the appropriate international forums. High levels of SCCP in biological samples from the Arctic indicate that these chemicals are effectively transported over long distances (CSTEE 1998) and a draft risk profile made for the Stockholm Convention in October 2008 mentions that: "SCCP are not expected to degrade significantly by hydrolysis in water, and dated sediment cores indicate that they persist in sediment longer than 1 year. SCCP have atmospheric half-lives ranging from 0.81 to 10.5 days, indicating that they are relatively persistent in air. SCCP have been detected in diverse environmental samples (air, sediment, water, wastewater, fish and marine mammals), and in remote areas such as the Arctic, providing evidence of long-range transport."

Tumours of the liver, thyroid and kidney (male rats only) were observed in a lifetime carcinogenic study in rats carried out in the US (Organohalogen Compounds, Volume 47, 2000).

It can be concluded that all environmental contamination of SCCP is likely to represent a widespread problem. This is due to the persistent, bioaccumulative and toxic (PBT), as well as the carcinogenic properties of SCCP. It can further be concluded that emissions from different, also diffuse sources, have the potential to reach the maritime area. On the basis of the accessibility of data on the amount of discharges, emissions and losses from several sources, it is not always possible to fully estimate the degree of risk to the marine environment. However, the absence of data to quantify emissions from each source should not be an obstacle to observing potential risks. Hence, the absence of quantifiable data does not eliminate a risk as such (OSPAR, 2009).

Potential to cause environmental harm may be estimated quantitatively using risk quotients (RQs). When RQs exceed 1 (i.e., in this case when Estimated Exposure Values (EEVs) exceed Estimated No-Effect Values (ENEVs)) this is an indication of potential for risk.

It is acknowledged, however, that when risks for persistent and bioaccumulative substances - such as SCCP, MCCP, and C18-20 LCCP - are determined using standard methods, the risks may be underestimated. For example, since it can take decades for persistent substances to achieve maximum steady state concentrations in sediment and soil, EEVs based on monitoring data will be too low if steady state concentrations have not been achieved in these media. Similarly, since it can take a long time for persistent and bioaccumulative substances to reach maximum steady state concentrations in the tissues of laboratory organisms, ENEVs based on standard toxicity tests may underestimate effect thresholds if test durations are insufficient to achieve maximum internal organism concentrations. Furthermore, since food consumption is usually the primary route of exposure to persistent and bioaccumulative substances in the field - especially for top predators - ENEVs may underestimate effect thresholds if the food pathway is not considered in key toxicity studies. These factors are exacerbated when available effects and exposure data are limited, as is the case for the chlorinated paraffins.

Risk quotients were calculated for SCCP, MCCP, C18-20 LCCP and C>20 LCCP (Table 7). For each identified class of risk receptors (e.g., pelagic organisms, benthic organisms), an EEV was selected based on empirical data. The maximum reported field concentration which is relevant to the Canadian environment was used as the EEV.

Chemical concentrations from the Canadian environment were preferably used for EEVs; however, data from other regions in the world were used in the absence of suitable Canadian data. Section 8.2 of the supporting document (Environment Canada, 2008) further discusses this point. An ENEV was determined by dividing a Critical Toxicity Value (CTV) by an assessment factor. CTVs, a detailed description is provide in Section 8.0 of the supporting document (Environment Canada, 2008), typically represent the lowest chronic ecotoxicity value from an available and acceptable data set. Assessment factors were used to reduce the CTV to account for extrapolation from a sometimes limited set of effects data for laboratory organisms, to estimates of effect thresholds for sensitive species in the field. Note that an extra assessment factor was not used to account for the tendency for conventional RQs to underestimate potential for harm for persistent and bioaccumulative substances. Results are summarized in Table 7.

Table 7. List of Estimated Exposure Values (EEV), Critical Toxicity Values (CTV), Assessment Factors (AF), and Estimated No Exposure Values (ENEV) used in the calculation of Risk Quotients (RQ) for SCCPs

Organism	EEV	CTV	AF	ENEV	RQ (EEV/ENEV)
Pelagic	**44.8[a] ng/L**	**8900[b] ng/L**	**10 (lab/field)**	**890 ng/L**	**0.05**
Benthic	**0.41[c] mg/kg**	**35.5[d] mg/kg**	**10 (lab/field)**	**3.55 mg/kg**	**0.12**
Soil-dwelling	**0.64[e] mg/kg**	**660[d] mg/kg**	**10 (lab/field)**	**66.0 mg/kg**	**0.01**
Secondary Consumer	**2.63[f] mg/kg**	**1000[g] mg/kg**	**100 (lab/field & species variations)**	**10 mg/kg**	**0.26**

[a] The highest concentration of SCCPs observed in final effluent of sewage treatment plants in southern Ontario was 448 ng/L at the Woodward Avenue sewage treatment plant in Hamilton, Ontario. A dilution factor of 10 was used to calculate the EEV which results in an EEV of 44.8 ng/L.

[b] 21-day LOEC for *Daphnia magna*

[c] Highest concentration in surface sediments observed from Lake Ontario, Niagara (or west) basin, in 1998.

[d] EC_{10} for *F. candida* reproduction.

[e] The maximum allowable rate for sewage biosolid application to agricultural lands is 8 tonnes of solids per hectare per 5 years (MOE 1998). The soil mass is 5000 tonnes/ha (assuming that the biosolids are incorporated into the top 20cm of soil having a dry soil bulk density of 2500 kg/m^3 (EU 2003)). Using a SCCP concentration in sewage sludge of 200 mg/kg dry wt. and assuming that SCCP-containing sludge is applied to the land for 10 years and that no or little biodegradation of the SCCP occurs, a soil concentration of 0.64 mg/kg dry wt is estimated.

[f] Concentratio of total SCCP found in carp from Hamilton Harbour in Lake Ontario.

[g] The LOAEL for the 13-week oral (gavage) rat study is 100 mg/kg bw/day (IRDC 1984). Interspecies scaling using this LOAEL for a typical adult otter (*lutra Canadensis*) (adult body weight of 8 kg and average daily food ingestion rate of 0.8 kg wet wt. per day) was used to extrapolate to a food concentration for this species (CCME 1998). The resulting CTV was 100 mg/kg food wet wt.

(Government of Canada, 2008).

Annex 2 – Details on final regulatory actions reported

Country Name: Norway

1	**Effective date(s) of entry into force of actions**	The regulation entered into force on January 2001. However, stock items imported or produced before January 2001 could be sold and used until January 2002. As stated in OSPAR decision 95/1, there is a transition period until January 2005 for conveyor belts used in the mining industry and for sealing materials in dams containing SCCP. (UNEP/FAO/RC/CRC.10/6 section 2.2.3).
	Reference to the regulatory document	"Regulation Governing Short Chain Chlorinated Paraffins", laid down by Ministry of the Environment 13 December 2000 with a legal basis in ACT no 79 of 11 June 1976 relating to product control, section 4.
2	**Succinct details of the final regulatory action(s)**	The regulatory action notified by Norway relates to the use of SCCP as industrial chemicals. The use of SCCP is banned by the final regulatory action which states that production, import, export, sale and use of SCCP in pure form, in preparations or in products containing > 0.1 % SCCP is prohibited (UNEP/FAO/RC/CRC.10/6 section 2, 2.2.1). Use for research and analytical purposes is still allowed (UNEP/FAO/RC/CRC.10/6 section 2.5.1).
3	**Reasons for action**	Risk for-long term effects to the aquatic environment. SCCP is also classified as category 3 carcinogen, i.e. there is limited evidence of carcinogenic effects. (UNEP/FAO/RC/CRC.10/6 Annex I, section 2.3).
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect the environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Norway.
4.1	**Risk evaluation**	SCCP are very toxic to aquatic organism, especially daphnia. They degrade slowly in the environment and have a high potential for bioaccumulation. Their negative long term effects in the aquatic environment, the risk secondary poisoning of predators through the food chain, and their potential for long range transport via air and water give rise to serious concerns for long-term effects to the aquatic environment. In the Norwegian notification, reference is made to the EU-RAR, which states that the use of short chain length chlorinated paraffins in metal working fluids and in leather finishing has been found to present a risk to aquatic organisms in surface water due to local exposures (European Communities, 2000).
4.2	**Criteria used Relevance to other States and Region**	Risk to the environment. High concentrations of SCCP in environmental media e.g. in the Baltic Sea, are reported. SCCP are recognized to be of possible concern with regard to long range atmospheric transport. It is concluded that similar environmental problems are likely to be encountered in other countries.
5	**Alternatives**	Though no information on alternatives for SCCP for Norway specifically were mentioned, general information on alternatives was included in the Norwegian supporting documentation (UNEP-FAO-RC-CRC.10-INF-10).
6	**Waste management**	The notifying Party did not provide information on waste management of SCCP.
7	**Other**	None

Country Name: Canada

1	**Effective date(s) of entry into force of actions**	March 14, 2013
	Reference to the regulatory document	*Prohibition of Certain Toxic Substances Regulations, 2012* Canada Gazette, Part II, Vol. 147, No.1- January 2, 2013.
2	**Succinct details of the final regulatory action(s)**	The regulatory action notified by Canada relates to the use of SCCP as industrial chemicals. The final regulatory action states that all manufacture, use, sale, offer for sale or import of SCCP or products containing them is prohibited, unless SCCP are incidentally present in the product or if they are used in a laboratory for analysis, in scientific research or as a laboratory analytical standard (UNEP/FAO/RC/CRC.10/6 section 2.1, 2.2.1 and 2.2.3).
3	**Reasons for action**	The regulatory action was based on concerns related to human health and environment.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and environment. The regulatory action was based on a risk evaluation taking into account the prevailing conditions in Canada.
4.1	**Risk evaluation**	The risk evaluation considered all Chlorinated Alkanes (CA), including SCCP, Medium-Chain Chlorinated Alkanes (MCCA) and Long-Chain Chlorinated Alkanes (LCCA). For SCCP, critical data relevant to both estimation of exposure of the general population in Canada and assessment of the weight of evidence for the mode of induction of specific tumours were identified following release of the first Priority Substances List (PSL1) assessment and prior to February 2001, although most of this information has been reported in incomplete published summary accounts or abstracts. These data suggest that several tumours observed in carcinogenicity bioassays in rats and mice exposed to SCCP are induced by modes of action either not relevant to humans (kidney tumours in male rats) or for which humans are likely less sensitive (in rats, liver tumours related to peroxisome proliferation and thyroid tumours related to thyroid-pituitary disruption). Complete documentation of available studies and consideration in additional investigations of the reversibility of precursor lesions in the absence of continued exposure is lacking. However, reported data on mode of induction of tumours in addition to the weight of evidence that SCCP are not DNA reactive are at least sufficient as a basis for consideration of a Tolerable Daily Intake (TDI) for non-cancer effects as protective for carcinogenicity for observed tumours. Upper-bounding estimates of daily intake of SCCP approach or exceed the TDI for these compounds, which, on the basis of available information, is likely also protective for potential carcinogenicity (UNEP/FAO/RC/CRC.10/6 section 2.4.2.1). On the basis of the available information, the latest assessment report from 2008 concludes that SCCP are entering, or may enter, the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health (UNEP/FAO/RC/CRC.10/INF/11, p. 184).
4.2	**Criteria used**	Risk to human health and environment.
	Relevance to other States and Region	The presence of SCCP in remote Arctic regions suggests that there is long-range atmospheric transport of SCCP. It is concluded that the considerations that led to the final regulatory action are applicable to a wide geographical area and circumstances.
5	**Alternatives**	Some alternatives were included in the supporting documentation (Environment Canada, Health Canada, 2008), for the following uses: metalworking fluids, polyvinyl chloride, paints and coatings, adhesives and sealants, and rubber and elastomers.
6	**Waste management**	The notifying Party did not provide information on waste management of SCCP.
7	**Other**	None

Annex 3 – Addresses of designated national authorities	
Norway	
Bjorg Fjeld **Norwegian Pollution Corntrol Authority** **Section for Chemicals and Metallurgical Industry** **PO Box 8100 Dep** **N – 0032 Oslo** **Norway** **+47 22 57 34 00** **Bjorg.fjeld@sft.no**	

Canada	
Ms. Lucie Desforges **Environment Canada** **351 St. Joseph Blvd. Gatineau, Quebec, K1A 0H3** **Canada** **819-938-4209** **Lucie.Desforges@ec.gc.ca**	

Annex 4 – References

Regulatory actions

Norway

Ministry of the Environment: Forskrift om kortkjedete klorparaffiner (Regulation Governing Short Chain Chlorinated Paraffins), laid down on 13 December 2000 with a legal basis in Act no 79 of 11 June 1976 relating to product control, section 4 (UNEP/FAO/RC/CRC.10/INF/10, p. 529-532)

Canada

Prohibition of Certain Toxic Substances Regulations (2012), Canada Gazette Part II, Vol. 147, No. 1 – January 2, 2013 ((UNEP/FAO/RC/CRC.10/INF/11, p. 3-25). Available at:
http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html)

Supporting documentation provided by Norway

Borgen, A. R., Schlabach, M., Mariussen, E. (2003). Screening of Chlorinated Paraffins in Norway. Organohalogen Compounds, Volume 60, pages 331-334.

European Communities (2000). European Union Risk Assessment Report, alkanes, C10-13, chloro, CAS No.: 85535-84-8, EINECS No.: 287-476. ISBN 92-828-8451-1. .

Norwegian Pollution Control Authority (SFT) (2001). Halogenerte organiske miljøgifter og kvikksølv i norsk ferskvannsfisk, 1995-1999 (Halogenated organic environmental chemicals and mercury in Norwegian freshwater fish, 1995-1999). SFT 4402-01, Rapport 827/01. (In Norwegian only).

Norwegian Pollution Control Authority (SFT) (2002). Kartlegging av bromerte flammehemmere og klorerte parafiner (Screening of brominated flame retardants and chlorinated paraffins). SFT TA-1924/2002, Rapport 866/02. (In Norwegian only).

Norwegian Pollution Control Authority (SFT) (1999). Kortkjedete høyklorerte paraffiner. Materialstrømsanalyse. (Short-chain highly chlorinated paraffins. Material Flow Analysis). SFT TA-1689/99, Rapport 99/24. (A cover page with a summary in English and first 4 pages of the document in Norwegian only).

Norwegian Pollution Control Authority (SFT) (1996). Overvåking av Hvaler-Singlefjorden og munningen av Iddefjorden 1990-1994. Miljøgifter i organismer. (Monitoring of environmental chemicals in organisms in fjord and coastal area 1990-1994, toxicants in organisms). SFT 3443-96, Rapport 651/96. (In Norwegian only).

OSPAR Commission (2009). Background Document on short chain chlorinated paraffins. Hazardous Substances Series.

OSPAR Commission (2001). Draft OSPAR Background Document on Short Chain Chlorinated Paraffins. ASMO 01/6/10 – HSC 01/5/6-E.

Supporting documentation provided by Canada

Government of Canada (2004a). Follow-up Report on a PSL1 Substance for Which Data Were Insufficient to Conclude Whether the Substance Was "Toxic" to Human Health Chlorinated Paraffins. Ottawa, Ontario.

Government of Canada (2004b). Follow-up Report on a PSL1 Substance for Which There Was Insufficient Information to Conclude Whether the Substance Constitutes a Danger to the Environment. Ottawa, Ontario.

Government of Canada (2008). Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health. Ottawa, Ontario.

Government of Canada (1993). Priority Substances List assessment report. Chlorinated paraffins. Minister of Supply and Services, Ottawa, Ontario (ISBN 0- 662-20515-4; Catalogue No. En40-215117E).

Government of Canada (2013). Prohibition of Certain Toxic Substances Regulations, 2012 (SOR/2012-285). Canada Gazette, Part II, Vol. 147, No. 1.

Environment Canada, Health Canada (2008). Proposed Risk Management Approach for Chlorinated Paraffins. Government of Canada, Ottawa.

Others

POPRC (2010). Supporting document for the draft risk profile on short-chained chlorinated paraffins. UNEP/POPS/POPRC.6/INF/15
POPRC (2012). Short-chained chlorinated paraffins. Revised draft risk profile. UNEP/POPS/POPRC.8/6

Relevant guidelines and reference documents

IARC (1990). Chlorinated paraffins. In: Some flame retardants and textile chemicals, and exposures in the textile manufacturing industry. Lyon, International Agency for Research on Cancer, pp 55-72 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 48). Available at: http://monographs.iarc.fr/ENG/Monographs/vol48/mono48-7.pdf

IMO (2013): International Maritime Dangerous Goods Code (IMDG code). Available at: http://www.imo.org/ourwork/safety/cargoes/pages/dangerousgoods.aspx

IPCS (1996): Environmental Health Criteria 181 "Chlorinated Paraffins". Available at: http://www.inchem.org/documents/ehc/ehc/ehc0181.htm

United Nations (2013): UN Recommendations on the Transport of Dangerous Goods - Model Regulations, Eighteenth revised edition. Available at: http://www.unece.org/trans/danger/publi/unrec/rev18/18files_e.html

UNITED NATIONS

UNEP

Food and Agriculture Organization of the United Nations

RC

UNEP/FAO/RC/CRC.11/3

Distr.: General
29 June 2015

Original: English

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Eleventh meeting
Rome, 26–28 October 2015
Item 5 (a) (ii) of the provisional agenda*
Technical work: consideration of draft decision guidance documents: tributyltin compounds

Draft decision guidance document for tributyltin compounds

Note by the Secretariat

I. Introduction

1. At its tenth meeting, taking into account the conclusion by the Chemical Review Committee that the notifications of final regulatory action for tributyltin compounds under the pesticide category submitted by Canada and the European Union met the criteria in Annex II to the Rotterdam Convention and recalling decision RC-4/5, by which the Conference of the Parties decided to amend Annex III to the Convention to list tributyltin compounds as pesticides, the Committee reviewed a notification of final regulatory action for tributyltin compounds under the industrial chemicals category submitted by Canada, together with the supporting documentation referenced therein, and concluded that the requirements set out in Annex II to the Convention had been met.

2. In its decision CRC-10/5, the Committee recommended that the Conference of the Parties list tributyltin compounds in Annex III to the Convention as industrial chemicals. By the same decision, the Committee adopted a rationale for its conclusions and agreed to establish an intersessional drafting group to revise the decision guidance document adopted by the Conference of the Parties in decision RC-4/5[1] to include information relevant to the industrial category.[2] A detailed workplan for the development of the decision guidance document was prepared by the Committee in line with the process adopted by the Conference of the Parties by decision RC-2/2 and amended by decisions RC-6/3 and RC-7/3. The recommendation, rationale and workplan were annexed to the report of the Committee on the work of its tenth meeting (UNEP/FAO/RC/CRC.10/10, annexes I and III).

3. The material available to the intersessional drafting group included a summary of the outcome of the tenth meeting of the Committee, a copy of a working paper on the preparation of internal proposals and decision guidance documents for banned and severely restricted chemicals and the notifications of final regulatory actions and associated supporting documentation available to the Committee at its tenth meeting.

* UNEP/FAO/RC/CRC.11/1.

[1] UNEP/FAO/RC/COP.4/10, annex V.

[2] The members of the intersessional drafting group were Ms. Anja Bartels (Austria), Mr. Gilberto Fillman (Brazil), Ms. Parvoleta Angelova Luleva (Bulgaria), Mr. Jeffery R. Goodman (Canada), Ms. Jinye Sun (China), Ms. Elsa Ferreras (Dominican Republic), Mr. Mohammed Ali Mohammed (Ethiopia), Mr. Omar S. Bah (the Gambia), Ms. Mirijam Kristina Brigitta Seng (Germany), Ms. Amal Al-Rashdan (Kuwait), Mr. Mohd Fauzan Yunus (Malaysia), Mr. Arturo Gavilán (Mexico), Mr. Jung-Kwan Seo (Republic of Korea), Ms. Tatiana Tugui (Republic of Moldova), Mr. Jürgen Helbig (Spain) and Ms. Nuansri Tayaputch (Thailand).

K1501971 270815

4. In accordance with the agreed workplan, the co-coordinators of the intersessional drafting group, Ms. Anja Bartels (Austria) and Ms. Parvoleta Angelova Luleva (Bulgaria), in consultation with the Secretariat, prepared an internal proposal to revise the decision guidance document adopted by the Conference of the Parties in decision RC-4/5[3] to include information relevant to the industrial category based on the notification and the supporting documentation. That internal proposal was circulated to the members of the drafting group for comments on 16 December 2014. It was amended in the light of the comments received and was circulated on 20 February 2015 to all Committee members and to the observers who had attended the tenth meeting. Responses were received from Committee members and observers and taken into consideration in the revision of the draft decision guidance document.

5. The outcomes of the work of the intersessional drafting group, including a compilation of the comments received and the draft decision guidance document, were circulated to the members of the drafting group on 5 May 2015.

6. The text of the draft decision guidance document is set out in the annex to the present note. It has not been formally edited. A tabular summary of comments received, including information on how they were addressed, is set out in document UNEP/FAO/RC/CRC.11/INF/8.

II. Proposed action

7. The Committee may wish to finalize the draft decision guidance document and to forward it, together with its recommendation to list tributyltin compounds in Annex III to the Convention as industrial chemicals, for consideration by the Conference of the Parties at its eighth meeting.

[3] UNEP/FAO/RC/COP.4/10, annex V.

Annex

Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Draft
Decision Guidance Document

tributyltin compounds

Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its fourth meeting, held in Rome on 27-31 October 2008 the Conference of the Parties agreed to list all tributyltin compounds in Annex III of the Convention under pesticides category and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure. The decision-guidance document related to that decision was communicated to designated national authorities on 1 February 2009 in accordance with Articles 7 and 10 of the Rotterdam Convention.

At its [...] meeting, held in [...] on [...], the Conference of the Parties agreed to list tributyltin compounds in Annex III of the Convention under industrial chemicals category, as well and adopted the revised decision-guidance document including both pesticides and industrial chemicals categories with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on [...], in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

---

[1] According to the Convention, the term "chemical" means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

[2] According to the Convention, the term "Party" means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to
µg	microgram
µm	micrometre
ARfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ATSDR	Agency for Toxic Substances Disease Registry
b.p.	boiling point
bw	body weight
°C	degree Celsius (centigrade)
CAS	Chemical Abstracts Service
cc	cubic centimetre
cm	centimetre
CSTEE	Scientific Committee for Toxicity, Ecotoxicity and the Environment (European Commission)
CTV	Critical Toxicity Value
DNA	deoxyribose nucleic acid
DT_{50}	dissipation time 50%
EINECS	European Inventory of Existing Commercial Chemical Substances
ECHA	European Chemicals Agency
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
g	gram
h	hour
ha	hectare
i.m.	intramuscular
i.p.	intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	median inhibitory concentration
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 1000)
kg	kilogram
Koc	soil organic partition coefficient.
Kow	octanol–water partition coefficient

STANDARD CORE SET OF ABBREVIATIONS	
kPa	kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	Lowest-observed-effect level
m	metre
m.p.	melting point
mg	milligram
mL	millilitre
mPa	millipascal
MRL	maximum residue limit
MTD	maximum tolerated dose
ng	nanogram
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect concentration
NOEL	no-observed-effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PNEC	predicted no effect concentration
Pow	octanol-water partition coefficient, also referred to as Kow
PPE	personal protective equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/L are used).
RfD	reference dose (for chronic oral exposure: comparable to ADI)
RTECS	Registry of Toxic Effects of Chemical Substances
SMR	standard(ized) mortality ratio
STEL	short-term exposure limit
TBT	tributyltin
TBTO	tributyltin oxide
TER	toxicity exposure ratio
TLV	threshold limit value
TWA	time-weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	ultraviolet
VOC	volatile organic compound
w/w	weight for weight
WHO	World Health Organization
wt	weight

Decision-guidance document for a banned or severely restricted chemical

Tributyltin (TBT) compounds[3] including: **Published: [...]**

Tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.

1. Identification and uses (see annex 1 for further details)

Common name

Tributyltin (TBT) compounds including: tributyltin oxide; tributyltin benzoate; tributyltin chloride; tributyltin fluoride; tributyltin linoleate; tributyltin methacrylate; tributyltin naphthenate.

Chemical name and other names or synonyms

Tributyltin oxide (TBTO)
IUPAC: hexabutyldistannoxane
CAS: bis(tributyltin)oxide

Tributyltin benzoate
IUPAC: (benzyloxy) tributyl stannane
CAS: tributyltin benzoate

Tributyltin chloride
IUPAC: tributyl-chloro stannane
CAS: tributyltin chloride

Tributyltin fluoride
IUPAC: tributyl-fluoro stannane
CAS: tributyltin fluoride

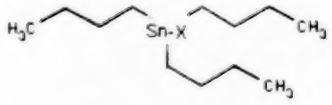
Tributyltin linoleate
IUPAC: tributyl-(1-oxo-9,12-octadecadienyl)oxy-stannane
CAS: tributyltin linoleate

Tributyltin methacrylate
IUPAC: tributyltin methacrylate
CAS: tributyl-(2-methyl-1 -oxo-2-propyl)oxystannane

Tributyltin naphthenate
IUPAC: tributyl-mono(naphthenoyloxy) stannane
CAS: tributyltin-- naphthenate

Chemical structure

Tributyltin derivatives $C_{12}H_{27}SnX$



[3] "TBT" is used in the present document to represent all tributyltin derivatives (or compounds), as the active form is the same for all compounds. "TBTO" is used where the information is specific to tributyltin oxide as in, for example, section 2 of annex 1, relating to toxicological properties.

CAS number(s)	Tributyltin oxide: 56-35-9 Tributyltin benzoate: 4342-36-3 Tributyltin chloride: 1461-22-9 Tributyltin fluoride: 1983-10-4 Tributyltin linoleate: 24124-25-2 Tributyltin methacrylate: 2155-70-6 Tributyltin naphthenate: 85409-17-2
Other CAS numbers that may be used	None
Harmonized System Customs Code	2931.20 (pure substance) 3808.50 (mixture)
Other numbers	**EC:** Index number 050-008-00-3 (common number for all TBT compounds) **EINECS:** Tributyltin oxide: 200-268-0; tributyltin benzoate: 224-399-8; tributyltin chloride: 215-958-7; tributyltin fluoride: 217-847-9; tributyltin linoleate: 246-024-7; tributyltin methacrylate: 218-452-4; tributyltin naphthenate: 287-083-9. **RTECS:** Tributyltin oxide: JN8750000; tributyltin benzoate: WH6710000; tributyltin chloride: WH6820000; tributyltin fluoride: WH8275000; tributyltin linoleate: WH8585000; tributyltin methacrylate: WH8692000.
Category	Pesticide, Industrial
Regulated category	Pesticide (Canada and European Union), Industrial chemical (Canada)
Use(s) in regulated category	Pesticide (Canada and European Union): Used in non-agricultural biocide pest control products. The most common use of TBT was in antifouling paints for ship hulls. It was also used as a biocide to prevent the fouling of appliances and equipment submerged in coastal and marine aquatic environments. TBT continues to be used in material and wood preservatives and as a slimicide. Industrial chemical (Canada): Tributyltins in their pure form are currently not in commercial use in Canada, but they may be found in products that are mainly used in the PVC processing industry, and as pesticides.Minor uses of products containing tributyltin compounds include glass coating and catalysts.
Trade names	Anti fouling paints: Intersmooth Hisol BFA253 SPC Interswift BKA007 Tri-Lux II T copolymer antifouling paint Manufacturing concentrates: BIOMET 303/60 Antifouling agent BIOMET 304/60 Antifouling agent BIOMET 300/60 Antifouling agent *This list is an indicative list of trade names. It is not intended to be exhaustive.*
Formulation types	Canada and European Union / pesticide: Formulated as paints Canada / industrial chemicals: Unknown
Uses in other categories	The European Union also reported uses in the industrial chemicals category, such as: use as an auxiliary agent in stereo selective intermediate synthesis in the pharmaceutical industry; use as a modifier for synthetic rubber polymers; and niche applications for some drugs.
Basic manufacturers	Pesticide: Witco GmbH (now Chemtura Organmetallics GmBH), Song Woun, Elf Atochem, Sigma Coatings, International Paints, Hempel, Jotun, Ameron, Chugoku and Kansai. *This is an indicative list of current and former manufacturers of TBT and TBT paints. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Tributyltin compounds (TBT) are included in the PIC procedure in both the pesticide and industrial category. The group of compounds is listed on the basis of the final regulatory actions that severely restrict their use as pesticide and industrial chemical, notified by Canada and the European Union.

2.1 Final regulatory action (see Annex 2 for further details)

Canada / pesticide: Registrations of all TBT-based antifouling paints, and the associated registered active ingredients and concentrates, were phased out by 31 October 2002. The registrant agreed to recall from the market all unsold stocks to ensure that there were no products in trade after 1 January 2003. There are no longer any TBT pesticides registered in Canada.

Reason: Environment (concerns with regard to non-target aquatic organisms, persistence in the environment and bioaccumulation in aquatic organisms).

European Union / pesticide: The use of TBT was prohibited, with effect from 1 January 2003, in: all paints and products to prevent the fouling of all craft intended for use in marine, coastal, estuarine and inland waterways and lakes; appliances and equipment used for fish or shellfish farming; any totally or partially submerged appliance or equipment; and industrial water treatment.

Reason: Human health and environment (concerns with regard to occupational exposure, consumption of contaminated food and risks to non-target aquatic organisms).

Canada / industrial chemical: Severe restriction of the manufacture, use, sale, offer for sale or import of non-pesticidal TBT compounds with the exemption of: a) tetrabutyltins containing a concentration of less than or equal to 30 % by weight of tributyltins; and b) mono- and dibutyltins, because tributyltins are incidentally present in these products. Entry into force of the final regulatory action was March 14, 2013.

Reason: Environment (concerns with regard to aquatic organisms, persistence in the environment and bioaccumulation in aquatic organisms).

2.2 Risk evaluation (see Annex 1 for further details)

Canada / Pesticide: Because of concerns regarding the impact of TBT (pesticidal use) on the aquatic environment, Canada had limited application of TBT antifouling paints to vessels greater than 25 metres in length and to vessels (of any length) with aluminium hulls, the latter because many non-tin alternatives contain forms of copper which can cause corrosion of aluminium hulls. A maximum daily tin release rate was imposed for these applications (1989).

These regulatory controls (*Pest Control Products Act*) were only partially effective in reducing concentrations of TBT in the aquatic environment. Monitoring for levels of TBT was undertaken in 1994. For some locations, TBT was found in freshwater much less frequently than in 1982–1985, and at much lower concentrations. In freshwater sediments, TBT was found at similar concentrations to those found a decade earlier, but was found more frequently. In seawater, TBT was found more frequently in 1994 compared to samples taken between 1982 and 1985. In every case, the concentrations exceeded acute and chronic toxicity endpoints, indicating a high potential for adverse effects in these particular locations. In marine sediments, TBT was found more frequently in 1994 than a decade earlier, and in about half of all marine sediments in which TBT was found, its concentration exceeded chronic toxicity thresholds, indicating a high potential for adverse effects in these particular locations.

Using the effect of imposex[4] on molluscs to monitor recovery from TBT contamination in Canadian waters, it was found that whelks (various species) before 1989 had high frequencies of imposex in the Juan de Fuca Strait and the Strait of Georgia, and lower frequencies on the west coast of Vancouver Island. By 1994, a reduction in imposex was evident on the west coast of Vancouver Island and in some locations in the Strait of Georgia. There was no clear evidence, however, of recovery near Victoria, and Vancouver Harbour did not have whelks in any abundance. Similarly, in Atlantic Canada, imposex in the dog whelk (*Nucella lapillus*) was found in 13 of 34 sites sampled in 1995. These results indicate that the regulatory control of TBT in antifouling paints in Canada had not eliminated the problem by 1995.

[4] Imposex is the development of male sexual characteristics by female organisms, which in severe cases can cause reproductive failure and death.

Because of the long persistence of TBT in sediment, TBT concentrations in marine sediments in some locations may exceed chronic toxicity thresholds for years to come.

In consideration of the foregoing, it was determined that the use of TBT in antifouling paints poses an unacceptable risk to Canadian waters, based on non-target toxicity to aquatic organisms, persistence in the environment and bioaccumulation in aquatic organisms.

The risk evaluation is based on TBT as the toxic species, rather than the specific tributyltin compounds that were registered in Canada (tributyltin oxide, tributyltin fluoride and tributyltin methacrylate). This evaluation is therefore valid for all tributyltin compounds.

European Union / Pesticide: The results of a study on the risks to health and to the environment of antifouling paints containing tin organic compounds were reviewed in November 1998 by the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission. Unacceptable risks were identified in the following areas:

Human health

Occupational: A health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere during mixing. Measurements of atmospheric concentrations at paint mixing plants have shown levels during the transfer period to be double the acceptable short-term occupational exposure limit, which is set at three times the value of the most stringent 8 hour time-weighted average (TWA). The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain.

Food consumption: A potential health risk was also identified from the ingestion of contaminated seafood. Using worst case values for bioaccumulation, daily fish consumption and acceptable daily intake (ADI), a TBT concentration in water necessary to keep the dietary exposure to TBT below acceptable daily intake levels was calculated. It was found that this concentration would be exceeded in areas close to shipping ports, although it was unlikely in more distant locations and the open sea. The use of TBT can result in concentrations in water that pose an unacceptable risk to human health where daily intake of fish comes from shellfish raised in waters near commercial harbours.

Environmental impact

Four exposure scenarios were examined and the predicted environmental concentration (PEC), predicted no effect concentration (PNEC) and PEC/PNEC ratios were identified for each of the following four environmental release scenarios:

1. Release to surface water from the manufacture of tributyltin oxide (TBTO);
2. Release to surface water from the manufacture of TBT self-polishing co-polymer paints;
3. Release to surface water from dockyard procedures;
4. Release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment.

Although it was not possible to determine the exact water concentrations arising from the release of TBT from shipping, sufficient evidence was available to suggest that, where shipping intensity was high, the PEC for TBT in surrounding water was greater than the PNEC, giving a ratio in all of the four exposure scenarios of >1, thus indicating an unacceptable environmental risk.

The freshwater environment was considered to be the most sensitive to TBT, because it has the most sensitive species and because TBT releases have greater potential for accumulation owing to lower rates of water exchange in lakes as compared to the open sea. Unacceptable environmental risk may also occur in other areas where exchange of water is low, which is common in large harbours such as in Rotterdam (where there is also a high influx of organic rich anoxic sediment) and in large bodies of brackish water such as the Baltic Sea.

It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. Releases of TBT from shipping, however, are more difficult to control because it has been shown that even when the TBTO release rate is reduced to the minimum required to maintain antifouling efficiency, the amount released from a large ship is still considerable. To reduce the TBT input from this source, it is necessary to restrict the use of TBT paints in the aquatic environment.

Canada / Industrial: A detailed review conducted by the government of Canada in 2009[5] concluded that non-pesticidal use of tributyltin compounds have toxic effects to aquatic organisms at low concentrations, and have a high potential to cause environmental harm due to their high persistence and bioaccumulative properties.

[5] "Government of Canada (2009). Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List. Ottawa, Ontario"

In the risk assessment a risk quotient was calculated on the basis of modelled as well as measured exposure and the toxicity. The exposure was based firstly, on concentrations of tributyltin compounds in water and sediment modelled for Canada, and secondly, on measured concentrations of tributyltin compounds in water and sediment in Canada. It was concluded that estimated and measured concentrations of non-pesticidal uses of tributyltins in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, tributyltins meet the criteria for persistence and bioaccumulation set out in Canada's national regulation, and high concentrations of tributyltin compounds in the environment, e.g. in the sediment, are known to cause imposex on molluscs and appear to have the potential to induce sex reversal in some marine fish.

The risk evaluation took into account that Canadian PVC processing facilities which use organotin stabilizers have adopted product stewardship practices that have led to a decrease in the quantity of organotins that could potentially be released to the environment. Because of the unique concerns relating to persistent and bioaccumulative substances, the potential for tributyltin compounds to cause environmental harm was evaluated separately from organotins as a group. The risk evaluation took into account these modelled and measured exposure data and the ecotoxicological endpoints for tributyltin compounds and indicates a high risk to the most sensitive aquatic organisms.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada / pesticide	The use of TBT in antifouling paints, which is the main source of TBT to the aquatic environment, was banned. Although persistence in the marine environment at some locations will cause it to remain elevated for some time, removing this source of input will allow recovery to occur.
European Union / pesticide	The ban of TBT in antifouling paints is expected to reduce significantly the input of TBT to the aquatic environment. Considering the long half time of degradation for TBT, it is likely that TBT will remain in the water column and sediment for up to twenty years after the cessation of TBT inputs to the environment. These residual concentrations should not present a threat to population sustainability.
Canada / industrial	The industrial use of TBT was banned with certain exceptions because there are other initiatives in place to manage any potential releases of these substances or these other uses have limited environmental impact. TBT's for non-pesticidal uses are not currently manufactured or used as pure substances in Canada. However, adding them to the Prohibition Regulations would prevent their introduction (and of products containing them) into the Canadian market, thereby eliminating the risk of their release to the aquatic environment.

3.2 Other measures to reduce exposure

The following initiatives are currently in place to manage any potential release of substances where TBTs may be present:

- An Environmental Performance Agreement 2015-2020 Respecting the Use of Tin Stabilizers in the Vinyl Industry is in place to manage the potential releases of mono- and di-organotins (referred to as tin stabilizers used in the vinyl industry) which may contain incidentally some TBT (this new agreement replaces the former one that covered the period of 2008-2013) http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=2F52E977;
- A Code of Practice (CoP)was published under section 54 of CEPA 1999 to manage releases of tetrabutyltin to the aquatic environment for all facilities involved with tetrabutyltin in Canada. Given that TBT may also be present incidentally in tetrabutyltin, this Code also indirectly manages the potential release of TBT.

General: The International Convention on the Control of Harmful Antifouling Systems on Ships prohibits the use of harmful organotins in antifouling paints used on ships and establishes a mechanism to prevent the potential future use of other harmful substances in antifouling systems. Under the terms of the Convention, Parties to the Convention are required to prohibit or restrict the use of harmful antifouling systems on ships. By 1 January 2008 (effective date), ships either:

- Shall not bear such compounds on their hulls or external parts or surfaces; or
- Shall bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant antifouling systems.

This applies to all ships (including fixed and floating platforms, floating storage units and floating production storage and offtake units).

3.3 Alternatives

It is essential that, before a country considers substituting alternatives, it ensures that the use is relevant to its national needs and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Canada / pesticide: Since 1989, several non-TBT antifouling paints have been evaluated and registered for use in Canada. These non-tin products contain copper active ingredients that offer antifouling properties similar to those of the TBT antifouling paints. Presently, there are more than 50 copper-based antifouling paints registered for use by either small ship owners or professional paint applicators. These copper antifouling paints offer protection periods ranging from 12 to 36 months. There are two copper thiocyanate products that are suitable for application on ships with aluminium hulls, as they do not cause corrosion like other copper-containing paints.

The International Convention on Control of Harmful Antifouling Systems on Ships requires that each Party undertakes to communicate information regarding any antifouling systems approved, restricted or prohibited under its domestic law. In order to fulfil this obligation, information is available on the website of Canada's Pest Management Regulatory Agency, at www.pmra-arla.gc.ca./english/intern/imo-e.html, which provides a listing of products registered in Canada.

European Union / pesticide: A number of alternative tin-free anti-fouling systems are commercially available (copper acrylate, other copper systems with or without booster, non-stick biocide-free products). Others are still under development (natural products extracts, e.g. sponge). The toxicity and the long-term environmental impact of all alternatives are not fully assessed. Several reviews, however, have been or are being carried out. The performances of most alternatives tend to be lower and the price is generally higher than that of TBT-based paints.

Canada / industrial chemical: PVC stabilizers: Substitutes for PVC tin stabilizers include lead or mixed metals such as calcium and zinc. Characteristics of lead stabilizers include low costs and well-documented environmental concerns. Lead stabilizers are currently being phased out in Europe. It is expected that lead will be replaced by lighter metals like calcium or zinc, as well as organic stabilizers. Mixed metal stabilizers are more expensive than their tin-based counterparts and are less effective in stabilization.
Use of Tributyltins as a Starting Material: Tributyltins are known to be used in the manufacture of other chemicals, one of which is a material preservative. Although no alternatives as a starting material are known to exist for this application, other non-tributyltin material preservatives registered under the *Pest Control Products Act* may be available.

3.4 Socio-economic effects

Canada / pesticide: There was no detailed assessment conducted on the socio-economic effects of the final regulatory action to ban the use of TBT based anti-fouling paints.

Organotin antifouling paints were registered for a range of antifouling needs including deep seagoing ships and smaller ships which travel primarily in coastal waters (e.g. ferries and sailboats with aluminium hulls). Registrations at the time of the regulatory action included three paint products (two of which had not been used in the previous year), the associated concentrates and the active ingredient tri-n-butyltin methacrylate. The only TBT antifouling paint that was in use at the time was labelled for use on ships with aluminium hulls. Based on information obtained from International Paint Co., at the time the regulatory action was taken, Canadian paint applicators were no longer applying TBT paints to vessels that travel in deep seawater. It was confirmed that past users of TBT paints, such as the Department of National Defence, were no longer applying tin products on their ships, which would indicate that adequate alternative paints were available.

European Union / pesticide: There was no detailed assessment conducted on the socio-economic effects of a severe restriction, although the risk evaluation suggested that a ban would have a significant cost to the economy. It should also be noted that, without antifouling, the fuel consumption of large ships may be increased by 50 per cent.

Canada / industrial: The severe restriction was not expected to result in any incremental costs to industry, as TBT compounds were not manufactured or used as industrial chemicals in their pure form in Canada and activity involving tributyltins which may be present in other compounds was not prohibited.

4. Hazards and risks to human health and the environment

4.1 Hazard classification

European Union	**CLP Classification** (Annex VI to Regulation (EC) 1272/2008): Acute Tox. 3, H301 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 **Classification** (Commission Directive 2004/73/EC of 29 April 2004): **T** toxic; **N** dangerous for the environment; **Xn** harmful; **Xi** irritant. **Risk phrases:** **R25** Toxic if swallowed **R48/23/25 Toxic** Danger of serious damage to health by prolonged exposure through inhalation and if swallowed. **R21** Harmful in contact with skin. **R36/38** Irritating to eyes and skin. **R50/53** Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

4.2 Exposure limits of TBTO

United States of America Environmental Protection Agency (USEPA 1997):

- Oral reference dose of 0.3 µg/kg body weight/day.

Agency for Toxic Substances Disease Registry (ATSDR 2005):

- Chronic oral minimal risk level of 0.3 µg/kg body weight/day.

World Health Organization (WHO 1999):

- Guidance value for oral exposure of 0.3 µg/kg body weight/day.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard class and packing group:	United Nations numbers: 2786, 2787, 2788, 3019, 3020, 3146 Hazard class: 6.1. Poisonous substance Packing group: II
International Maritime Dangerous Goods Code	Severe marine pollutant.
Transport emergency card	61G41 (Organotin pesticide, solid)

4.4 First aid

Note: The following advice is based on information available from the World Health Organization and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Signs and symptoms of acute poisoning include abdominal cramps, cough, diarrhoea, laboured breathing, nausea, vomiting and redness and pain at point of exposure.

First aid procedures:
Inhalation: Fresh air, rest. Half-upright position. Seek medical attention.
Skin: Rinse and then wash skin with water and soap. Seek medical attention.
Eyes: First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to doctor.
Ingestion: Induce vomiting (only in conscious persons). Give plenty of water to drink. Seek medical attention.

International Programme on Chemical Safety (IPCS) (2004). International safety card on tributyltin oxide, available at www.inchem.org/pages/icsc.html.

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticide stocks the guidelines available include the FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (1995), the FAO Pesticide Storage and Stock Control Manual (1996) and the FAO/WHO/UNEP Guidelines for the Management of Small Quantities of Unwanted and Obsolete Pesticides (1999).

Canada and the European Union adopted the same risk management strategy to deal with the existing stocks, by allowing a short phase-out period following adoption of their regulatory actions. This was seen as the lowest risk option for disposing of existing stocks in the light of risk associated with product recall, storage and disposal. It also allowed users time to change over to alternatives (see annex 2 to the present document).

In all cases, waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, any guidelines thereunder and any other relevant regional agreements.

It should be noted that the recommended disposal and destruction methods are often not available in, or suitable for, all countries, e.g. high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in the FAO/WHO/UNEP Technical Guidelines for the Disposal of Bulk Quantities of Obsolete Pesticides in Developing Countries (1996).

In the event of spillage of TBTO, do not wash away into a sewer. Carefully collect the remainder, then remove it and take it to a safe place. Do not let TBTO enter the environment. Wear a chemical protection suit, including self-contained breathing apparatus.

Annexes

Annex 1	**Further information on the substance**
Annex 2	**Details of final regulatory action**
Annex 3	**Address of designated national authorities**
Annex 4	**References**

Annex 1 Further information on the substance

Introduction

The information presented in the present annex reflects the conclusions of two Parties notifying TBTs as pesticides, namely Canada and the European Union, and one Party, Canada, notifying TBTs as industrial chemicals. Where possible, information provided by these Parties on hazards has been presented together, while the risk assessments, which are specific to the use category and the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions banning tributyltin compounds. The notification from Canada as pesticide was first reported in PIC Circular XXII of December 2005, the notification from the European Union (at that time it was the European Community) in PIC Circular XVII of June 2003 and the notification from Canada as industrial chemicals was published in PIC Circular XXXVIII of December 2013.

There have been two reviews on TBT, both published by WHO: the International Programme on Chemical Safety Environmental Health Criteria, No. 116: Tributyltin compounds (1990); and the Concise International Chemical Assessment Document, No. 14: Tributyltin oxide (1999). The two reviews had been taken into consideration in the final regulatory actions relating to the pesticide category of Canada and the European Union and are referenced in the present document. Some conclusions from these reviews have been used in the present document, for example, those relating to carcinogenicity and neurotoxicity set out in section 2.2. These do not differ substantially from the information provided by the notifying Parties.

Further information - tributyltin compounds

1. Physico-chemical properties

1.1	**Identity**	Data for tributyltin oxide is provided as the most commonly reported form used in antifouling paints. In seawater, tributyltin compounds exist as three species (hydroxide, chloride and carbonate) under normal conditions. Similar data for other forms are available.
1.2	**Formula**	Tributyltin oxide (TBTO): $C_{24}H_{54}OSn_2$; Tributyltin benzoate: $C_{19}H_{32}O_2Sn$; Tributyltin chloride: $C_{12}H_{27}ClSn$; Tributyltin fluoride: $C_{12}H_{27}FSn$; Tributyltin linoleate: $C_{30}H_{58}O_2Sn$; Tributyltin methacrylate: $C_{16}H_{32}O_2Sn$; Tributyltin naphthenate: $C_{23}H_{34}O_2Sn$.
1.3	**Molecular weight**	596.07 g
1.4	**Appearance**	Colourless liquid
1.5	**Boiling point**	173°C
1.6	**Melting point**	<-45°C
1.7	**Density (g/cm^3)**	1.17 at 20 °C
1.8	**Vapour pressure, Pa at 20°C**	$1x10^{-3}$ Pa at 20°C
1.9	**Flash point**	190°C
1.10	**Solubility in water**	71.2 mg/L at 20°C (1–100 mg/L, depending on pH, temperature, anions)
1.11	**Solubility in organic solvents**	TBTO is soluble in lipids and very soluble in a number of organic solvents (ethanol, ether, halogenated hydrocarbons)
1.12	**Log Pow**	3.19–3.84 (distilled water), 3.54 (sea water)
1.13	**Decomposition**	>230°C

(Atkins International Ltd. 1998; IPCS, 1990)

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of action**	Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT and, as such, a number of acceptable and tolerable daily intake values have been determined for this endpoint. The cell-mediated function is impaired due to effects on the thymus. The mechanism of action is unknown but may involve the metabolic conversion to dibutyltin compounds. Non-specific resistance is also affected (IPCS, 1990).

2.1.2 Symptoms of poisoning

Effect of short-term exposure is severe irritation to the eyes and the skin. Inhalation of the aerosol may cause lung oedema which often does not become apparent until several hours have passed. They are exaggerated by physical effort. TBTO[6] may cause effects on the thymus, resulting in depression of the immune function (IPCS, 2004).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

TBT is absorbed through the gut (20–50%) and via the skin of mammals (about 10%), and can be transferred across the blood-brain barrier. Absorbed material is rapidly and widely distributed amongst tissues (principally liver and kidneys; IPCS, 1990).

2.2 Toxicology studies

2.2.1 Acute toxicity

LD_{50} (rat, oral): 94–234 mg/kg bw (TBT)
LD_{50} (rat, oral): 165–277 mg/kg bw (TBTO)
LD_{50} (mouse, oral): 44–230 mg/kg bw (TBT)
LD_{50} (rabbit, dermal): > 9000 mg/kg bw (TBT)
LC50 (rat, inhalation, 4 h): 65 mg/L bw (TBTO, respirable particles)
(IPCS, 1990)

Tributyltin is moderately to highly toxic in laboratory animals via the oral route. Effects of acute exposure have been reported to include alterations in blood lipid levels, the endocrine system, liver and spleen and transient deficits in brain development. Acute dermal toxicity is low. TBT is very hazardous as an inhaled aerosol, producing lung irritation and oedema, but is relatively innocuous as a vapour. It is severely irritating to the skin and is an extreme irritant to the eye but does not appear to be a skin sensitizer. Severe dermatitis can result after direct contact with TBT concentrations greater than 0.01% (IPCS, 1990).

2.2.2 Short term toxicity

In short and long-term studies, structural effects on endocrine organs, mainly the pituitary and thyroid, have been reported. Changes in circulating hormone concentrations and altered response to physiologic stimuli (pituitary trophic hormones) have been reported primarily in short-term studies, suggesting some adaptive response with prolonged exposure. The liver and bile duct have also been identified as target organs on the rat, mouse and dog with short-term oral exposure. Likewise, effects on erythrocyte parameters leading to anaemia have been documented in rats and mice (IPCS, 1990).

The most characteristic toxic effect is on the immune system. Due to effects on the thymus, cell-mediated function is impaired; non-specific resistance is also affected. While effects on the immune system of rats and dogs have been reported, the rat appears to be the most sensitive species tested, particularly with effects on host resistance to infection following short-term oral exposure. It has been postulated that TBT is metabolized to a more active dibutyltin salt. The dibutyltin then impedes the maturation of immature thymocytes by inhibiting action or binding with thymic epithelial cells (IPCS, 1990).

Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT, and as such, acceptable daily intake (ADI) values have been determined for this endpoint. The setting of ADI values is discussed in section 2.2.7.

2.2.3 Genotoxicity (including mutagenicity)

There is no evidence that TBTO has any mutagenic potential (IPCS, 1990).

A wide range of both in vitro and in vivo mutagenicity assays have been carried out on TBTO with the conclusion that there is no convincing evidence that TBTO has any mutagenic potential (IPCS 1990).

[6] Data applying to TBTO is principally reported, as this was the main chemical form used in anti-fouling paints. TBTO is hydrolysed to TBT ions in the water column. The principal forms of TBT in the aquatic environment are hydroxides, chlorides and carbonates, the proportion of each depending on the properties of the water body (e.g. pH, salinity). TBT in the aquatic environment is in the same form regardless of the TBT compound from which it was derived.

2.2.4	**Long term toxicity and carcinogenicity**	In a two-year rat test, TBTO was considered to have produced no relevant malignant tumours at oral concentrations of up to 50 mg/kg body weight/day. The presence of elevated numbers of tumours in the endocrine organs (pituitary and adrenal in both sexes, parathyroid in males only) at lower doses and kidney and pancreatic tumours were not considered biologically relevant, as there was no dose dependent response (IPCS, 1990). TBTO was not carcinogenic in a study in mice (IPCS, 1999). There is insufficient evidence to suggest that TBTO is a possible human carcinogen (IPCS, 1990).
2.2.5	**Effects on reproduction**	In developmental studies in the rat, rabbit and mouse, no sensitivity of the foetuses was observed. Malformations (i.e. cleft palate) were noted in rat and mouse foetuses, but only at doses that were overtly toxic to the mothers. TBTO is not considered to be teratogenic. The lowest no-observed effect level (NOEL), with regard to embryotoxicity and foetotoxicity for mice, rats and rabbits, was 1.0 mg/kg body weight (IPCS, 1990). Little information is available on reproductive toxicity but it appears that TBT did not affect reproductive parameters in a rat multi-generation reproduction study (IPCS, 1990).
2.2.6	**Special studies where available** **Neurotoxicity/ delayed neurotoxicity**	There is no evidence that neurotoxicity is likely to be a critical effect (IPCS, 1999).
2.2.7	**Summary of mammalian toxicity and overall evaluation**	TBT has moderate to high acute oral toxicity, low dermal toxicity and is very hazardous as inhaled aerosols resulting in lung irritation and oedema. They are severely irritating to the skin and extremely irritating to the eye. TBT leads to endocrine changes in experimental animals, particularly to pituitary trophic hormones. The most characteristic toxic effect is on the immune response, with effects on cell mediated function due to effects on the thymus. Immune system impairment has been determined to be the most sensitive parameter for systemic effects of TBT, and as such, a number of acceptable and tolerable daily intake values have been determined based on this toxic endpoint. There is no convincing evidence of mutagenicity and insufficient data to suggest carcinogenic potential in humans. It is not considered to be teratogenic but there is little information on reproductive effects. Neurotoxicity is not likely to be a critical effect. The effects of TBT on the immune system, and particularly on host resistance, have proved the most sensitive parameter of toxicity in the rat, the most sensitive species tested. The no-observed effect level (NOEL), for immuno-suppression following long-term oral exposure in rats is 0.025 mg/kg body weight/day (IPCS 1999). Based on the application of an uncertainty factor of 100, WHO proposed a guidance value for oral exposure of 0.3 µg/kg body weight/day (IPCS, 1999). USEPA currently reports a guidance value of 0.3 µg/kg body weight/day based on a benchmark does analysis (BMD10) of the same study data. (USEPA, 1997). The ADI used by Atkins International Ltd. (1998) in its assessment for the European Union was 1.6 µg/kg body weight/day (CSTEE, 1998). This figure was derived from a NOEL-based on a different toxicological endpoint (lymphoid weight and function studies). In the final decision, the European Union adopted an ADI of 0.3 µg/kg body weight/day based on the same NOEL and endpoint as the WHO.

3 Human exposure/risk evaluation

3.1 Food

The risk evaluation of Canada suggested that data were inadequate to characterize meaningfully the total intake of organotin compounds from food.

The risk evaluation of the European Union identified a potential health risk from the ingestion of contaminated seafood. Using an exposure scenario with a value for bioaccumulation of 7000 (*Mytilus edulis*), a daily fish intake of 115 g and an acceptable daily intake value of 1.6 µg/kg body weight/day, it was calculated that the quantity of TBT that would be consumed by a man weighing 70 kg would be in the order of 112 µg. Calculating back from this value, it was determined that, in order to keep consumption of TBT at or below this level, the concentration in water should be in the order of 139 ng/L. It was considered that this concentration could be exceeded in areas close to the shipping ports, although it was unlikely in more distant locations and the open sea. If the consumption estimate was repeated with the more conservative ADI of 0.3 µg/kg body weight/day, the concentration in water would correspondingly be lower.

Therefore, the level of TBT use may pose an unacceptable risk to human health where daily intake of fish comes from shellfish raised in waters near commercial harbours.

3.2 Air

Data on the concentration of organotin compounds in either indoor or ambient air were not identified in the risk evaluation of Canada.

While systematic review of exposure to air has not been undertaken, the risk evaluation of the European Union identified inhalation exposure during the mixing of ingredients in the manufacture of antifouling paint to be a potential risk to human health.

3.3 Water

Levels of TBT released from shipping and from use in dockyards can result in levels in water in the ng/L range. A potential risk was identified by the European Union from the consumption of fish and shellfish raised in water contaminated with TBT.

Human exposure to TBT through the consumption of water containing residues in the ng/L range is considered negligible.

3.4 Occupational exposure

Occupational exposure of workers to TBT has resulted in irritation of the upper respiratory tract, severe dermatitis and eye irritation. The lack of an immediate dermal response exacerbates this potential hazard.

WHO describes skin lesions, dermatitis and skin and eye irritancy in workers exposed dermally to TBT and irritation of the upper respiratory tract and lower chest symptoms in rubber vulcanizing workers using TBTO (IPCS, 1990).

In the risk evaluation of the European Union, a health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere during mixing. Measurements of atmospheric concentrations at paint mixing plants have shown levels during the transfer period of 0.049 to 0.195 mg/m^3 as TBT. This exposure only occurs for approximately 15 minutes, however it can be over double the acceptable short-term occupational exposure limit of 0.072 mg/m^3 set at three times the value of the most stringent 8-hour time-weighted average (TWA: 3 x 0.024 mg/m^3). The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain.

3.5 Medical data contributing to regulatory decision

The effects of TBT in humans are not well documented, except for the induction of apoptosis in granulocytes and human thymocytes. No information has been located regarding toxicity of TBTO in humans following oral exposure. Summary of the human data suggests that TBTO is a potent non-allergenic dermal irritant (see section 3.4 above). Impairment of the immune system is considered the most sensitive parameter for systemic effects of TBT.

There have been no cases of acute systemic poisoning (IPCS, 1990).

3.6	**Public exposure**	No detailed risk evaluations of public exposure have been undertaken by Canada or the European Union, other than the potential risk to consumers of fish and shellfish raised in waters contaminated with TBT.
3.7	**Summary-overall risk evaluation**	Occupational exposure of workers to TBT has resulted in irritation of the upper respiratory tract, severe dermatitis and eye irritation. The lack of an immediate dermal response exacerbates this potential hazard. In the risk evaluation of the European Union, a health risk was identified from the mixing of TBT-based paints due to the release of TBT to the atmosphere. The use of protective equipment during this operation is likely to reduce the level of exposure to acceptable limits but the use of such equipment is uncertain. Levels of TBT released from shipping and from use in dockyards can result in levels in water in the ng/L range. A potential risk was identified by the European Union from the consumption of fish and shellfish raised in areas close to shipping ports contaminated with TBT. Human exposure to TBT through the consumption of water containing residues in the ng/L range was considered negligible.

4 Environmental fate and effects

4.1	**Fate**	
4.1.1	**Soil**	There are no soil persistence values in the risk evaluations of the notifying countries.
4.1.2	**Water**	Irrespective of their original structure, tributyltin compounds exist in seawater as three species (hydroxide, chloride and carbonate) under normal conditions. TBT slowly degrades to dibutyltin and monobutyltin in the aquatic environment (Atkins International Ltd., 1998). Levels of TBT released from shipping result in levels in water in the ng/L range. Persistence of TBT in water is slight to moderate with a half-life in water reported as a few days to a few months.
4.1.3	**Air**	No available data.
4.1.4	**Bioconcentration/ Bioaccumulation**	Studies with algae, aquatic invertebrates and fish have confirmed that bioaccumulation of TBT in these organisms is substantial. The bioconcentration factor (BCF) values reach up to 10000 in periwinkles, 50000 in fish, and 500000 in clams. Tributyltins are highly bioaccumulative, with reported BAFs (bioaccumulation factor) of up to 900000. Concentrations in tissues of top predators are also high (up to 4 µg/g wet weight). Limited evidence of biomagnification has been reported for some marine food chains with biomagnification factors typically less than 10 (Government of Canada, 2009).
4.1.5	**Persistence**	The persistence of TBT in water is slight to moderate with half-lives of a few days to a few months. TBT shows significant persistence in sediments, however. Several studies from different parts of the world indicate half-lives for TBT in sediment of up to 15 years. The levels of TBT in the sediments of dockyards around the world varies widely from 10–2000 µg/kg dry weight (Atkins International Ltd., 1998).
4.2	**Effects on non-target organisms**	
4.2.1	**Terrestrial vertebrates**	There have been few detailed studies on terrestrial species. WHO reports that exposure to terrestrial organisms results primarily from its use as a wood preservative. There was some indication of toxicity to bats exposed topically or via feeding on treated wood. TBT is moderately toxic to wild mice (IPCS, 1990).

4.2.2	**Aquatic species**	TBT is toxic to many aquatic organisms. Mollusc: LC_{50} (48h, adult *Mytilus edulis)* = 300 µg TBTO/L LC_{50} (66d, juvenile *Mytilus edulis)* = 0.97 µg TBT/L LC_{50} (48h, larvae *Mytilus edulis)* = 2.3 µg TBTO/L Fish: LC_{50} (96h, *Salmo gairdneri)* = 3.44 µg TBTO/L NOEC (90 day, *Poecilia reticulata*) = 0.01 µg hexabutyldistannoxane /L (Atkins International Ltd., 1998) The 110-day Lowest-Observable-Effect Concentration (LOEC) for rainbow trout (*Oncorhynchus mykiss*) yolk sac fry was 0.173 µg tributyltin chloride/L, based on increased mortality and decreased resistence to *Aeromonas*. Tributyltins are toxic at low concentrations. Furthermore, several specific modes of toxic action are possible, including endocrine disruption (Government of Canada, 2009). *Daphnia magna*: NOEC (21 d) = 0.078 µg TBT/L (Atkins International Ltd., 1998) *Hexagenia spp.* LC_{50} (mayfly, 21-d, sediment): 1.5 µg TBTchloride/g dry weight, based on growth (Government of Canada, 2009) Bacteria: EC_{10} (18h, *Pseudomonas putida)* = 24 µg TBT/L (Atkins International Ltd., 1998) Effects on the shell development of the Pacific oyster *(Crassostrea gigas)* have been observed at concentrations < 2 ng TBT/L (Atkins International Ltd., 1998). Chronic effects on benthos may occur at TBT concentrations in the range of 0.1-1 µg/g dry weight of sediment (Government of Canada, 2009). Some marine benthic invertebrates are also very sensitive to TBT in sediments. Populations of benthic invertebrates such as polychaetes and amphipods have been shown to be reduced as a result of exposure to TBT in sediments (Maguire, 2000).The dog whelk (*Nucella lapillus)* has been shown to suffer from imposex at TBT concentrations at less than 1 ng TBT/L. This impairment of reproduction was also observed in numerous other marine species (Maguire, 2000).
4.2.3	**Honeybees and other arthropods**	TBT is toxic to bees housed in hives made from wood treated with TBT. There was some indication of toxicity to insects exposed topically or via feeding on treated wood.
4.2.4	**Earthworms**	No available data
4.2.5	**Soil microorganisms**	No available data
4.2.6	**Terrestrial plants**	No available data

5 Environmental exposure/risk evaluation

5.1	**Terrestrial vertebrates**	No risk evaluation
5.2	**Aquatic species**	**Canada / pesticide:** TBT is an exclusively anthropogenic chemical. A detailed review concluded that TBT is extremely toxic to aquatic organisms, and is sufficiently persistent (half- life of up to 15 years in sediment) and bioaccumulative (BCF values up to 500000) to warrant further regulatory action. The dog whelk (*Nucella lapillus)* has been shown to suffer from imposex at TBT concentrations at less than 1 ng TBT/L. TBT has been detected in surface water at levels greater than 1 ng/L thus representing an unacceptable risk to non-target aquatic species. It was determined that the continued use of TBT in antifouling paints poses an unacceptable risk to the Canadian environment, based on toxicity to non-target aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.

Because of the long persistence of TBT in sediment, TBT concentrations in marine sediments in some locations may exceed chronic toxicity thresholds for years to come.

European Union / pesticide: In the risk evaluation of the European Union, four aquatic exposure scenarios were examined and the predicted environmental concentration (PEC), predicted no effect concentration (PNEC) and PEC/PNEC ratios were identified for each of the identified releases to the aquatic environment. The PNEC derived for freshwater, based on toxicity to freshwater snails (*Biomphalaria glabrata*), was 0.024 ng/L and for marine water, based on toxicity to the dog whelk (*Nucella lapillus*), 1.2 ng/L. The four scenarios were:

1. Release to surface water from the manufacture of TBTO;
2. Release to surface water from the manufacture of TBT self-polishing co-polymer paints;
3. Release to surface water from dockyard procedures;
4. Release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment.

Table 1: PEC, PNEC and PEC:PNEC ratio for each of the aquatic exposure scenarios (Atkins International Ltd., 1998)

Release source	PEC (ng/L)	PNEC (ng/L)	PEC:PNEC
Manufacture of TBTO	17.5	0.024	729
Manufacture of TBT self-polishing co-polymer paints	2	0.024	83
Release of TBT from dockyard into freshwater	20	0.024	833
Release of TBT from dockyard into marine water	2	1.2	1.6
Release from shipping over 25m into marine water	>1.2[1]	1.2	>1
Release from shipping over 25m into brackish water	>1.2[1]	1.2	>1
Release of TBT from shipping over 25m into freshwater	>1[1]	0.024	>40

[1]Not able to quantify

In this evaluation, PEC, PNEC and PEC/PNEC ratios were derived for each of the aquatic exposure scenarios. Sufficient evidence was available to suggest that where shipping intensity is high and in dockyards, the potential concentration of TBT in the surrounding waters represented by the PEC is greater than the PNEC (derived from no effect levels on sensitive species together with an assessment factor: the dog whelk (*Nucellus lapillus)* for marine water and freshwater snails (*Biomphalaria glabrata)* for freshwater) giving a ratio in all the above areas of >1, thus indicating an unacceptable environmental risk.

It was concluded that releases of TBT to the aquatic environment from shipping and dockyards are difficult to control. The minimum TBTO release rate required to maintain antifouling efficiency still resulted in a substantial release to the aquatic environment in the case of large ships. To reduce the TBT input to the aquatic environment from this source, it would be necessary to restrict the use of TBT antifouling paints.

Canada / industrial chemical: A detailed review conducted by the government of Canada (Proposed risk management approach for Non-Pesticidal Organotin Compounds (Organotins), 2009) concluded that tributyltin compounds are toxic to aquatic organisms at low concentrations, and have a high potential to cause environmental harm due to their high persistence and bioaccumulative properties.

In the risk assessment a risk quotient was calculated on the basis of modelled as well as measured exposure and the toxicity. The exposure was based firstly, on concentrations of tributyltin compounds in water and sediment modelled for Canada, and secondly, on measured concentrations of tributyltin compounds in water and sediment in Canada. It was concluded that estimated and measured

concentrations of tributyltins in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, tributyltins meet the criteria for persistence and bioaccumulation set out in Canada's national regulation, and high concentrations of tributyltin compounds in sediments are known to cause imposex (imposition of male characteristics on female organisms) on molluscs and appear to have the potential to induce sex reversal in some marine fish.

Although risk quotients may also be used to indicate potential to cause environmental harm for persistent and bioaccumulative substances, risks are likely to be underestimated using this approach. For example, if steady state has not been achieved in the environment and concentrations are continually increasing, measured PECs (Predicted Environmental Concentrations) will be too low. In addition, PNECs (Predicted No Effect Concentrations) may be too high because of the long time needed to achieve steady state and the lack of exposure through food consumption in typical short-term laboratory toxicity tests.

Nevertheless, risk quotients for tributyltins were calculated for comparison purposes. PEC/PNEC ratios for tributyltin compounds, based on both modelled and measured PECs in water and sediment, are shown in Table 2. The Canadian Water Quality Guideline for the Protection of Freshwater Aquatic Life of 0.008 µg/L was used as the PNEC for tributyltins in water. The most sensitive benthic organism reported was the mayfly, *Hexagenia* spp., with a 21-day IC_{50} (growth) of 1.5 mg tributyltin/kg dry weight. Dividing this toxicity value by an assessment factor of 100 (10 to extrapolate from an acute to a chronic no-effect level, and 10 to account for extrapolation from laboratory to field conditions and for inter- and intraspecies variability) gives a chronic PNEC of 0.015 mg/kg dry weight for tributyltins in sediment. All risk quotients in Table 2 are significantly greater than 1, thus indicating a potentially high risk.

Table 2: PEC/PNEC Ratios for Tributyltin Substances

	PEC	CTV	PNEC	PEC/PNEC
Water: modelled PEC[a]	0.22 µg/L	--	0.008 µg/L	**28**
Water: measured PEC[b]	0.043 µg/L	--	0.008 µg/L	**5.4**
Sediment: modelled PEC[a]	7.8 mg/kg dry weight	1.5 mg/kg dry weight	0.015 mg/kg dry weight	**520**
Sediment: measured PEC[b]	2.4 mg/kg dry weight	1.5 mg/kg dry weight	0.015 mg/kg dry weight	**160**

[a] highest environmental concentrations predicted for new and/or transitional tributyltins associated with chemical manufacturing, expressed as hydrolysed tributyltin

[b] highest concentration measured in Canada (Follow-up report on a PSL1 substance . . 2003)

5.3 Honey bees

No risk evaluation

5.4 Earthworms

No risk evaluation

5.5 Soil microorganisms

No risk evaluation

5.6 Summary – overall risk evaluation

Canada / pesticide: It was concluded that the use of TBT in antifouling paints posed an unacceptable risk to the Canadian environment, based on toxicity to non-target aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.

European Union / pesticide: Unacceptable risks to non-target aquatic organisms were identified in the release to surface waters both from the manufacture of TBT and TBT-containing antifouling paints and the hulls of ships painted with antifouling paints.

Canada / industrial chemical: It was concluded that the use of TBT as an industrial chemical posed an unacceptable risk to the Canadian environment, based on toxicity to aquatic organisms, persistence in the environment, and bioaccumulation in aquatic organisms.

Annex 2 – Details of final regulatory actions reported

Category: Pesticide

Party name: Canada

1	**Effective date(s) of entry into force of actions**	31 October 2002
	Reference to the regulatory document	Pest Management Regulatory Agency special review decision on tributyltin antifouling paints for ship hulls (SRD2002-01). (http://www.hc-sc.gc.ca/contact/order-pub-commande-eng.php?title=PMRA%20%28srd2002-01%29%20Tributyltin%20Antifouling%20Paints%20for%20Ship%20Hulls).
2	**Succinct details of the final regulatory action(s)**	The registrations of all tri-n-butyl tin-based TBT antifouling paints, and their associated registered concentrates and active ingredient, were phased out during 2002. The registrant agreed to conduct a recall of any unsold product to ensure that there is no product in the channels of trade after 1 January 2003.
3	**Reasons for action**	Using the effect of imposex on molluscs to monitor recovery from TBT contamination, studies indicated that regulatory control of TBT antifouling paints in Canada prior to 1999 had not eliminated the problem. It was determined that the continued use of TBT in antifouling paints posed an unacceptable risk to non-target aquatic organisms. Because of the long persistence of TBT in sediment, TBT concentrations in marine sediments in some locations may exceed chronic toxicity thresholds for years to come.
4	**Basis for inclusion into Annex III**	Final regulatory action that severely restricts the use of TBT compounds based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	The review concluded that there were unacceptable risks to the aquatic environment. For more details please see Annex I, 5.2.
4.2	**Criteria used**	Risks to the environment.
	Relevance to other States and Region	TBT anti-fouling paints can cause harm to the aquatic environment. Preventing use on ship hulls therefore protects the aquatic environment from this exposure wherever such ships may travel.
5	**Alternatives**	Since 1989, several non-TBT antifouling paints have been evaluated and registered for use in Canada. These non-tin products contain copper active ingredients that offer antifouling properties similar to those of the TBT antifouling paints. Presently, there are more than 50 copper-based antifouling paints registered for use by either small ship owners or professional paint applicators. These copper antifouling paints offer protection periods ranging from 12 months to 36 months. There are two copper thiocyanate products that are suitable for application on ships with aluminium hulls, as they do not cause corrosion like other copper-containing paints.
6	**Waste management**	No specific measures outlined.
7	**Other**	Non-pesticidal organotin compounds were included on the first priority substances list under the 1988 Canadian Environmental Protection Act for assessment of potential risks to the environment and human health. The non-pesticidal organotin compounds considered in the assessment were primarily those of monomethyltin, dimethyltin, monobutyltin, dibutyltin, mono-octyltin and dioctyltin. Non-pesticidal organotin compounds are imported into Canada mainly for use as stabilizers during the processing of polyvinylchloride (PVC) resins and as industrial catalysts. The assessment of effects on the environment focused on aquatic biota since they are most likely to be exposed to non-pesticidal organotin compounds. On the basis of available data, non-pesticidal organotin compounds are not considered to have adverse effect to the Canadian environment. Furthermore, the compounds that were assessed are not volatile and are not expected to contribute to phenomena such as

ozone depletion, global warming, or the formation of ground-level ozone. It was concluded that, based on available data, non-pesticidal organotin compounds are not entering the environment in a quantity or conditions that may constitute a danger to human health or life. The assessment report recommended that future uses of these compounds should continue to be monitored, to ensure that exposure does not increase to any significant extent, and any relevant data should be considered upon development of more sensitive testing strategies for endocrine disrupting effects.

Party name: European Union

1	**Effective date(s) of entry into force of actions**	The regulatory action entered into force on 12 July 2002. The Member States of the European Union were required to apply the measures as from 1 January 2003.
	Reference to the regulatory document	Commission Directive 2002/62/EC of 9 July 2002 adapting to technical progress for the ninth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (organostannic compounds) (Official Journal of the European Communities (OJ) L183 of 12 July 2002, p. 58) (available at http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_183/l_183220020712en00580059.pdf). Other relevant regulatory actions: Council Directive 89/677/EEC of 21 December 1989 (OJ L398 of 30/12/1989, p. 19), Commission Directive 1999/51/EC of 26 May 1999 (OJ L142 of 5/06/1999, p. 22).
2	**Succinct details of the final regulatory action(s)**	As from 1 January 2003, the use of tri-organostannic compounds, including TBT compounds, is banned in all paints and products to prevent the fouling of all craft intended for use in marine, coastal, estuarine and inland waterways and lakes; appliances and equipment used for fish or shellfish farming; any totally or partially submerged appliance or equipment; and in industrial water treatment.
3	**Reasons for action**	In the risk assessment conducted for the European Commission, unacceptable health risks were identified in the following areas: **Human health** • Occupational: Inhalation and dermal exposure to atmospheric TBT during the transfer of ingredients to the mixing vessel during antifouling paint manufacture. • Food consumption: Ingestion of contaminated food (e.g. mussels) where TBT concentrations are high. It was concluded that the occupational risk arising from manufacture and application processes may be reduced by increased control of the process. Releases of TBT to the aquatic environment from shipping, however, are more difficult to control because it has been shown that even when the TBTO release rate is reduced to the minimum required to maintain antifouling efficiency, the amount released from a large ship is still considerable. **Environmental impact** 1. Release to surface water from the manufacture of TBT; 2. Release to surface water from the manufacture of TBT self polishing co-polymer paints; 3. Release to surface water from dockyard procedures; 4. Release to surface water from the use of TBT on ships in the marine, brackish or freshwater environment. It was concluded that the risk arising from manufacture and application processes may be reduced by increased control of the process. Releases of TBT from shipping, however, are more difficult to control because it has been shown that, even when the TBT release rate is reduced to the minimum required to maintain antifouling efficiency, the amount released from a large ship is still considerable. To reduce the TBT input from this source, it was necessary to restrict the use of TBT paints in the aquatic environment.

4	**Basis for inclusion in Annex III**	Final regulatory action to severely restrict use of TBT based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	The evaluation concluded that there were unacceptable risks to human health and to the environment.
4.2	**Criteria used**	Risks to human health and the environment.
	Relevance to other States and regions	Protection of the aquatic environment and human health. Global relevance is confirmed by the International Convention on the Control of Harmful Anti-fouling Systems. This includes a global prohibition on the application or reapplication of organotin compounds which act as biocides in anti-fouling systems on ships by 1 January 2003. It also requires that, by 1 January 2008, ships either shall not bear such compounds on their hulls or shall bear a coating that forms a barrier to such compounds leaching from the underlying non-compliant anti-fouling systems.
5	**Alternatives**	A number of alternative tin-free antifouling systems are commercially available (copper acrylate, other copper systems with or without booster, non-stick biocide-free products). Others are still under development (extracts of natural products, e.g. sponge).
6	**Waste management**	No specific measures outlined
7	**Other**	Commission Directive 2002/62/EC is the latest in a series of regulatory actions, dating back to 1989, when use of TBT in treatment of industrial waters was banned, because large quantities of water are used in many installations such as cooling systems, power station cooling towers, pulp and paper mills leading to significant releases in surface water, and when controls on antifouling applications were first introduced. These latter restrictions have progressively been extended. Use of TBT in free association paints was banned in 1999. In this type of paint, the TBT is only physically incorporated into the paint matrix and has a significant potential for early release. Commission Directive 2002/62/EC extended the ban to all other forms of antifouling products.

Category: Industrial

Party name: Canada

1	**Effective date(s) of entry into force of actions**	14 March 2013
	Reference to the regulatory document	*Prohibition of Certain Toxic Substances Regulations, 2012* *Canada Gazette*, Part II, Vol. 147 No. 1 – Jan. 2, 2013 http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html
2	**Succinct details of the final regulatory action(s)**	Severe restriction of the use of TBT compounds. All manufacture, use, sale, offer for sale or import is prohibited with the exception of: a) tetrabutyltins containing a concentration of less than or equal to 30 % by weight of tributyltins; and b) mono- and dibutyltins, because tributyltins are incidentally present in these products.
3	**Reasons for action**	Protection of the environment. Tributyltins are harmful to many aquatic organisms at low concentrations. They are present in the environment as a result of human activity. They have been shown to impose male sexual characteristics on females of some marine gastropods and appear to have the potential to induce sex reversal in some marine fish. Estimated and measured concentrations of tributyltins in some locations in Canada are high enough to cause adverse effects in sensitive organisms. Furthermore, non-pesticidal use of tributyltins meet the criteria for persistence and bioaccumulation set out in the *Persistence and Bioaccumulation Regulations*, a regulation made under the *Canadian Environmental Protection Act, 1999*.
4	**Basis for inclusion into Annex III**	Final regulatory action that severely restricts the use of TBT compounds based on a risk evaluation taking into consideration local conditions.
4.1	**Risk evaluation**	The risk evaluation took into account industry stewardship practices. In light of this, and with consideration of the persistent and bioaccumulative properties of tributyltins, the review concluded that there were unacceptable risks to aquatic organisms.
4.2	**Criteria used**	Risks to the environment.
	Relevance to other States and Region	TBT can cause harm to the aquatic environment. Preventing input from industrial uses protects the aquatic environment from this exposure.
5	**Alternatives**	No information was presented in the Notification of Final Regulatory Action. The supporting information provided the following on alternatives: PVC Stabilizers: Substitutes for PVC tin stabilizers include lead or "mixed metals" such as calciumzinc. Mixed metal stabilizers are more expensive than their tin-based counterparts and are less effective in stabilization Tributyltins are known to be used in the manufacture of other chemicals, one of which is a material preservative. Although no alternatives as a starting material are known to exist for this application, other non-tributyltin material preservatives registered under the *Pest Control Products Act* may be available.
6	**Waste management**	No specific measures outlined.
7	**Other**	

Annex 3 – Addresses of designated national authorities

Canada
P

Pest Management Regulatory Agency, Health Canada
2720 Riverside Drive
Ottawa, Ontario K1A 0K9
Trish MacQuarrie
Director, Alternative Strategies and Regulatory Affairs Division

Phone +1 613-736-3660

Fax +1 613-736-3659

E-mail trish_macquarrie@hc-sc.gc.ca

European Union
CP

Directorate General Environment, Unit D3-Chemicals, Biocides, Nanomaterials
European Commission
Avenue de Beaulieu 9
Office BU 9, 05/166
B-1049 Brussels
Belgium
Jürgen Heinrich Helbig
Principal Policy Officer

Phone +322 298 8521

Fax +322 298 8874

E-mail Juergen.Helbig@ec.europa.eu

Canada
C

Environment Canada
351 St. Joseph Blvd., Gatineau
Quebec, K1A 0H3
Ms. Lucie Desforges
Director, Chemical Production Division

Phone +1 819-938-4209

Fax +1 819-938-4218

E-mail Lucie.Desforges@ec.gc.ca

CP Pesticides and industrial chemicals
P Pesticides
C Industrial chemicals

Annex 4 – References

Regulatory actions

Commission Directive 2002/62/EC of 9 July 2002 adapting to technical progress for the ninth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (organostannic compounds) (Official Journal of the European Communities (OJ) L183 of 12/07/2002, p.58) (available at: http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_18320020712en00580059.pdf).

Council Directive 89/677/EEC of 21 December 1989 (OJ L398 of 30/12/1989, p.19).

Commission Directive 1999/51/EC of 26 May 1999 (OJ L142 of 5/06/1999, p.22).

PMRA (2002). *Pest Management Regulatory Agency special review decision: Tributyltin anti-fouling paints for ship hulls* (SRD2002-01). (available by request at http://www.hc-sc.gc.ca/contact/order-pub-commande-eng.php?title=PMRA%20%28srd2002-01%29%20Tributyltin%20Antifouling%20Paints%20for%20Ship%20Hulls).

Prohibition of Certain Toxic Substances Regulations, 2012. Canada Gazette, Part II, Vol. 147 No. 1 – Jan. 2, 2013 (http://www.gazette.gc.ca/rp-pr/p2/2013/2013-01-02/html/sor-dors285-eng.html).

Other documents

Atkins International Ltd. (1998). Risk Assessment for the European Commission. *Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use*. W.S. Atkins International Ltd. (vol. A), April 1998.

ATSDR (2005). Agency for Toxic Substances and Disease Registry. *Toxicological profiles: Tin and tin compounds* (available at: http://www.atsdr.cdc.gov/).

CSTEE (1998). *Opinion on the report by W.S. Atkins International Ltd. (vol. A): Assessment of the risks to health and to the environment of tin organic compounds in anti-fouling paint and of the effects of further restrictions on their marketing and use*. Opinion expressed at the sixth CSTEE plenary meeting, Brussels, 27 November 1998 (available at: http://europa.eu.int/comm/food/fs/sc/sct/out26_en.html).

Environment Canada, Health and Welfare Canada (1993) *Priority substances list assessment report: Non-pesticidal organotin compounds* (available at: www.hc.sc.gc.ca/hecs-sesc/exsd/pdf/non_pesticial_organotin_compound...pdf).

Follow-up report on a PSL1 substance for which data were insufficient to conclude whether the substance was toxic to human health – non-pesticidal organotin compounds, May 2003 (available at: www.hc.gc.ca/substances/ese/eng/psap/assessment/PSL1_organotin_followup.pdf).

Government of Canada (2009). Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List. Ottawa, Ontario.

International Convention on the Control of Harmful Anti-fouling Systems on Ships (available at: http://www.imo.org/home.asp?topic_id=161).

IPCS (1990). *Environmental Health Criteria No. 116 Tributyltin Compounds*. WHO, Geneva (available at http://www.inchem.org/documents/ehc/ehc/ehc116.htm).

IPCS (1999). *Concise International Chemical Assessment Document 14: Tributyltin Oxide*. WHO, Geneva (available at: http://www.inchem.org/pages/cicads.html).

IPCS (2004). *International chemical safety card: tributyltin oxide* (available at: http://www.inchem.org/pages/icsc.html).

Maguire (2000). *Review of the persistence, bioaccumulation and toxicity of tributyltin in aquatic environments in relation to Canada's toxic substances management policy*, R. James Maguire, Water Quality Research Journal, Canada, 2000, Volume 35, No.4, 633-679.

USEPA (1997). United States Environmental Protection Agency Integrated Risk Information System (IRIS) (available at: http://www.epa.gov/iris).

Relevant guidelines and reference documents

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996) (available at: www.basel.int).

FAO (1990). Guidelines for personal protection when working with pesticides in tropical countries. FAO, Rome (available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/).

FAO (1995). Revised guidelines on good labelling practices for pesticides. FAO, Rome (available at: http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/list-guide-new/en/)

FAO (1995). Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks. FAO, Rome (available at: http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/).

FAO (1996). Technical guidelines on disposal of bulk quantities of obsolete pesticides in developing countries. FAO, Rome (available at: http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/)

FAO (1996). Pesticide Storage and Stock Control Manual. FAO, Rome (available at: http://www.fao.org/agriculture/crops/obsolete-pesticides/resources0/en/)